

EXHIBIT 1

UNITED STATES DISTRICT COURT

for the
District of Delaware

APPLE INC.,

Plaintiff

v.

MASIMO CORPORATION and
SOUND UNITED, LLC,

Defendant

Civil Action No. 22-1378-MN-JLH

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Mr. Harnik Shukla, Esq.,
Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, California 92614

(Name of person to whom this subpoena is directed)

☒ **Testimony:** YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must promptly confer in good faith with the party serving this subpoena about the following matters, or those set forth in an attachment, and you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about these matters: See Schedule A attached hereto.

Place: Regus Conference Center 445 S. Figueroa Street, Suite 2600 & 2700 Los Angeles, CA 90071	Date and Time: 09/19/2023 10:00 am
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The deposition will be recorded by this method: Stenographically, audiotaped, and videotaped

☒ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material: See Schedule A attached hereto. Documents to be produced on or before September 6, 2023, to:
Jordan N. Malz, Desmarais LLP, 230 Park Avenue, New York, NY 10169
jmalz@desmaraisllp.com

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 08/22/2023

CLERK OF COURT

OR

/s/ Jordan N. Malz

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Plaintiff Apple Inc.

, who issues or requests this subpoena, are:
Jordan N. Malz | Desmarais LLP | 230 Park Ave., New York, NY 10169 | 212-351-5497 | jmalz@desmaraisllp.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 22-1378-MN-JLH

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____
on *(date)* _____ .

☐ I served the subpoena by delivering a copy to the named individual as follows: _____

_____ on *(date)* _____ ; or

☐ I returned the subpoena unexecuted because: _____
_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____ .

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
 - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below whenever used in any Definition, Instruction, Request for Production, or Deposition Topic.

1. As used herein, the terms “You” or “Your” means Harnik Shukla.
2. As used herein, “Apple” means Apple Inc., all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.
3. As used herein, “Masimo” means Masimo Corporation and all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on its behalf.
4. As used herein, “Sound United” means Sound United, LLC (a/k/a Masimo Consumer) and all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on its behalf.
5. As used herein, “Cercacor” means Cercacor Laboratories Inc. and all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on its behalf.
6. As used herein, “Masimo Asserted Patents” means U.S. Patent No. 10,687,743 (“the ’743 Patent”), U.S. Patent No. 10,722,159 (“the ’159 Patent”), U.S. Patent No. 8,190,223

(“the ’223 Patent”), U.S. Patent No. 10,736,507 (“the ’507 Patent”), and U.S. Patent No. 10,984,911 (“the ’911 Patent”).

7. As used herein, “Related Masimo Publications” means any patent, patent application, or patent application publication in the same patent family as any of the Masimo Asserted Patents, including any patent in the priority chain of the Masimo Asserted Patents, and all patent applications related to the Masimo Asserted Patents and any patents in the same family as any of the Masimo Asserted Patents, including any patent application in the priority chain of the Masimo Asserted Patents.

8. As used herein, “Patent Office” means the United States Patent and Trademark Office.

9. As used herein, “Inequitable Conduct References” means all references that are the subject of Apple’s inequitable conduct allegations in this case, including without limitation (1) U.S. Pub. No. US2011/0004106 to Iwamiya et al.; (2) U.S. Patent No. 6,801,799 to Mendelson; (3) U.S. Patent No. 6,343,223 to Chin et al.; (4) U.S. Patent No. 5,099,842 to Mannheimer et al.; (5) U.S. Patent No. 6,580,086 to Schulz et al.; (6) U.S. Patent No. 6,816,241 to Grubisic; (7) U.S. Patent No. 5,782,756 to Mannheimer; (8) U.S. Patent No. 5,638,816 to Kiani et al.; (9) U.S. Patent No. 5,203,329 to Takatani et al.; (10) Nellcor pulse oximeter products, including the NPB-195, N-395, and OxiMax N-595 products; (11) Mendelson et al., “A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring,” Proceedings of the 28th IEEE EMBS Annual International Conference, August 30-September 3, 2006 (“Mendelson IEEE”); and (12) any other references that Apple contends were withheld or the subject of “burying” in its response to Your Interrogatory No. 23 (*see* Ex. 1).

10. As used herein, “Medtronic” means Medtronic PLC, Covidien, Nellcor Puritan Bennett Inc., Mallinckrodt Inc., and all of their predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

11. As used herein, “Nellcor Prior Art Products” refers to all pulse oximeter and/or watch products made or sold by Medtronic before September 22, 2020. By way of example and not limitation, “Nellcor Prior Art Products” includes (1) all versions of Nellcor OxiMax pulse oximetry sensors, including without limitation all versions of the Nellcor OxiMax sensors such as those described in Exhibits 2 and 3, such as the Nellcor DS-100A; (2) the Nellcor N-595 Pulse Oximeter (*see, e.g.,* Ex. 2); (3) the Nellcor N-395 Pulse Oximeter, including without limitation the Nellcor N-395 Pulse Oximeter Masimo accused of infringement in at least *Masimo Corp. v. Mallinckrodt Inc., et al*, 8:99-cv-01245 (CDCA) (*see also* *Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App’x 158, 164 (Fed. Cir. 2005)); (4) the Nellcor NPB-195 Pulse Oximeter (*see, e.g.,* Ex. 4); (4) the Nellcor N-3000 (*see, e.g.,* Ex. 5); (5) the Nellcor Oxinet II Monitoring System (*see, e.g.,* Ex. 6); (6) the Nellcor Oxinet III Monitoring System (*see, e.g.,* Ex. 7); and (7) the Nellcor NPB-295 Monitor.

12. As used herein, the term “document” shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and includes the original and every non-identical copy or reproduction in Your possession, custody, or control, and further is used in a broad sense to refer to any electronically stored information (“ESI”) or any tangible object or thing that contains, conveys, or records information.

13. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

14. As used herein, “person” means any natural person or any business, legal, or governmental entity or association.

15. As used herein, “include” and “including” shall be construed to mean “without limitation,” so as to give the broadest possible meaning to interrogatories and definitions containing those words.

16. As used herein, “and” and “or” shall be construed conjunctively and disjunctively so as to acquire the broadest meaning possible.

17. As used herein, “any” and “all” shall each be construed to mean “each and every,” so as to acquire the broadest meaning possible.

18. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

19. As used herein, “related” or “relating” to any given subject means, without limitation, identifying, describing, discussing, concerning, assessing, stating, reflecting constituting, containing, embodying, tending to support or refute, or referring directly or indirectly to, in any way, the particular subject matter identified.

20. As used herein, “identify” as applied to a document shall mean to specify: (a) the type of the document (i.e., whether it is a letter, memorandum, e-mail, etc.); (b) the document’s title and general subject matter; (c) the number of pages of the document; (d) the date the document was prepared; (e) the name of each and every author, addressee, distributor, and recipient of the document; (f) the date each distributor distributed the document and the date each recipient received the document; and (g) the name of each person that has or had possession, custody, or control of the document.

21. Any term not specifically defined herein shall be defined in accordance with normal usage as well as with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

1. Apple's Requests for Production seek responsive documents and information sufficient to answer each of the Requests that are known or available to You or in Your possession, custody, or control. If, after exercising due diligence to secure the documents or information requested, You cannot fully respond to a Request for Production, state that such is the case and answer to the fullest extent possible, stating what responsive documents or information are available, what documents or information cannot be provided, why the documents or information are unavailable, and what efforts were made to obtain the unavailable documents or information. If documents or information responsive to a Request in this subpoena are in Your control, but not in Your possession or custody, promptly identify the entity with possession or custody.

2. Regardless of whether a production is in electronic or paper format, documents that were maintained together before production should be produced in the same form, sequence, organization, or other order or layout as they were maintained, including any labels, file folders, file jackets, covers, or containers in which such documents are located or with which such documents are associated. If copies of documents are produced in lieu of the originals, such copies should be legible and bound or stapled in the same manner as the original.

3. These Requests for Production shall be deemed continuing. Documents located, and information learned or acquired, at any time after Your response is due must be promptly supplemented at the place specified in this subpoena.

4. A copy of the Protective Order entered in this Action for the protection of any requested proprietary, confidential, or commercially sensitive information is attached hereto.

REQUESTS FOR PRODUCTION

1. All documents referring or relating to the preparation, filing, and/or prosecution of each of the Masimo Asserted Patents, U.S. Patent No. 10,687,745, and the other Related Masimo Publications.

2. All documents relating to Your efforts to comply with the duty to disclose information material to the patentability under 37 C.F.R. § 1.56 during the prosecution of each Masimo Asserted Patent and Related Masimo Publications, including without limitation Your determinations relating to what to disclose and not disclose to the Patent Office during these prosecutions.

3. All documents referring, relating to, or showing Your awareness or involvement in the preparation, filing, and/or prosecution of each of the Masimo Asserted Patents, U.S. Patent No. 10,687,745, and the other Related Masimo Publications.

4. All documents referring or relating to each Inequitable Conduct Reference, including without limitation all documents referring to, relating to, or showing Your awareness of the Inequitable Conduct References.

5. All documents referring or relating to Your involvement in *Mallinckrodt, Inc. v. Masimo Corp.*, No. 2:00cv-06506 (C.D. Cal.); *Masimo Corp. v. Mallinckrodt Inc.*, Nos. 8:01-cv-00638 & 2:01-cv-07292 (C.D. Cal.); *Nellcor Puritan, et al. v. Masimo Corp.*, Nos. 8:02-cv-01133 & 2:03-cv-00603 (C.D. Cal.), including without limitation all declarations, affidavits, transcripts of testimony, and other submissions provided by or referring to You.

6. All documents relating to whether any Nellcor Prior Art Products infringe any Masimo, Cercacor, or Sound United Patent, including without limitation all infringement contentions in the following litigations: *Mallinckrodt, Inc. v. Masimo Corp.*, No. 2:00cv-06506

(C.D. Cal.); *Masimo Corp. v. Mallinckrodt Inc.*, Nos. 8:01-cv-00638 & 2:01-cv-07292 (C.D. Cal.); and *Nellcor Puritan, et al. v. Masimo Corp.*, Nos. 8:02-cv-01133 & 2:03-cv-00603 (C.D. Cal.).

7. All communications with Masimo, Cercacor, and/or Sound United regarding the Masimo Asserted Patents and Related Masimo Publications.

8. All documents referring or relating to any search results, including patentability, validity, prior-art, infringement, or state-of-the-art searches, concerning the Masimo Asserted Patents and Related Masimo Publications.

9. All agreements between You and Masimo, Cercacor, and/or Sound United.

EXEMPLARY DEPOSITION TOPICS

By way of example and not limitation, the following exemplary topics are among those that will be covered at the deposition:

1. The preparation, filing and prosecution of each of the Masimo Asserted Patents, U.S. Patent No. 10,687,745, and the other Related Masimo Publications, including without limitation the identity of all individuals involved in these prosecutions.

2. Your efforts to comply with the duty to disclose information material to the patentability under 37 C.F.R. § 1.56 during the prosecution of each Masimo Asserted Patent and Related Masimo Publications, including without limitation Your determinations relating to what to disclose and not disclose to the Patent Office during these prosecutions.

3. Your determinations relating to what to disclose and not disclose to the Patent Office during prosecution of each of the Masimo Asserted Patents and Related Masimo Publications.

4. Your awareness or involvement in the preparation, filing, and/or prosecution of each of the Masimo Asserted Patents, U.S. Patent No. 10,687,745, and the other Related Masimo Publications.

5. Your knowledge and awareness of the Inequitable Conduct References during prosecution of the Masimo Asserted Patents.

6. The reasons why the Nellcor NPB-195, N-395, and OxiMax N-595 were not disclosed to the Patent Office during prosecution of the '223 patent.

7. The reasons why Mendelson IEEE was not disclosed to the Patent Office during prosecution of the '507 patent.

8. The reasons over 1,000 references were disclosed to the Patent Office during each of the prosecutions of the '743 patent, the '159 patent, and the '911 patent, respectively.

9. Your communications with Masimo, Cercacor, or Sound United regarding the Masimo Asserted Patents and Related Masimo Publications.

10. Your search results, including patentability, validity, prior-art, infringement, or state-of-the-art searches, concerning the Masimo Asserted Patents or Related Masimo Publications.

11. Executed agreements between You and Masimo, Cercacor, or Sound United.

12. The subject matter contained within the documents produced in response to the Requests For Production herein, including the authentication thereof.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APPLE INC.,)	
)	
Plaintiff,)	
)	C.A. No. 22-1377-MN-JLH
v.)	
)	JURY TRIAL DEMANDED
MASIMO CORPORATION and)	
SOUND UNITED, LLC,)	
)	
Defendants.)	
<hr/>		
MASIMO CORPORATION,)	
)	
Counter-Claimant,)	
)	
v.)	
)	
APPLE INC.,)	
)	
Counter-Defendant.)	
<hr/>		
APPLE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 22-1378-MN-JLH
)	
MASIMO CORPORATION and)	JURY TRIAL DEMANDED
SOUND UNITED, LLC,)	
)	
Defendants.)	
<hr/>		
MASIMO CORPORATION and)	
CERCACOR LABORATORIES, INC.,)	
)	
Counter-Claimants,)	
)	
v.)	
)	
APPLE INC.,)	
)	
Counter-Defendant.)	

**AGREED PROTECTIVE ORDER
REGARDING THE DISCLOSURE AND USE OF DISCOVERY MATERIAL**

Plaintiff and Counter-Defendant Apple Inc. (“Plaintiff”), Defendants and Counter-Claimants Masimo Corporation and Sound United, LLC and Counter-Claimant Cercacor Laboratories, Inc. (together, “Masimo”) anticipate that documents, testimony, or information containing or reflecting confidential, proprietary, trade secret, and/or commercially sensitive information are likely to be disclosed or produced during the course of discovery, initial disclosures, and supplemental disclosures in these cases and request that the Court enter this Order setting forth the conditions for treating, obtaining, and using such information.

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court finds good cause for the following Agreed Protective Order Regarding the Disclosure and Use of Discovery Material (“Order” or “Protective Order”).

1. **PURPOSES AND LIMITATIONS**

(a) Protected Material designated under the terms of this Protective Order shall be used by a Receiving Party solely for these cases, and shall not be used directly or indirectly for any other purpose whatsoever.

(b) The Parties acknowledge that this Order does not confer blanket protections on all disclosures during discovery, or in the course of making initial or supplemental disclosures under Rule 26(a). Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party’s attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify all other Parties that it is withdrawing or changing the designation.

(c) Other Proceedings. By entering this order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a request or motion that would require disclosure of another party's information designated "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," pursuant to this Order shall promptly notify that party of the request or motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

2. DEFINITIONS

(a) "Affiliate" means any corporation, company, or other business entity over which a Party has the power to direct or cause the direction of the management, policies, or legal actions through: (1) at least 50% ownership of voting securities; or (2) contract; or (3) other means.

(b) "Discovery Material" means all items or information, including from any non-party, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery or Rule 26(a) disclosures in these cases.

(c) "Outside Counsel" means (i) outside counsel who appear on the pleadings as counsel for a Party and (ii) partners, associates, and staff of such counsel to whom it is reasonably necessary to disclose the information for this litigation.

(d) "Patents-in-suit" means U.S. Patent Nos. D735,131, D883,279, D947,842, D962,936, 10,076,257, 10,627,783, 10,942,491, 10,987,054, 11,106,352, 11,474,483, 10,912,501, 10,912,502, 10,945,648, 10,687,743, 10,687,745, 10,722,159, 7,761,127, 8,190,223, 10,736,507,

(f) “Producing Party” means any Party or non-party that discloses or produces any Discovery Material in these cases.

(h) “Receiving Party” means any Party who receives Discovery Material from a Producing Party.

AGREED PROTECTIVE ORDER – PAGE 4

disclosure and review restrictions in Section 11. Still images of CAD files may be designated as “CONFIDENTIAL” or “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” as provided for in this Order.

3. **COMPUTATION OF TIME**

The computation of any period of time prescribed or allowed by this Order shall be governed by the provisions for computing time set forth in Federal Rules of Civil Procedure 6.

4. **SCOPE**

(a) The protections conferred by this Order cover not only Discovery Material governed by this Order as addressed herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.

(b) Nothing in this Protective Order shall prevent or restrict a Producing Party’s own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.

(c) Nothing in this Order shall be construed to prejudice any Party’s right to use any Protected Material with the consent of the Producing Party or by order of the Court.

(d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

(e) Any use of Protected Material at trial shall be governed by the orders of the trial judge and other applicable authorities. This Order does not govern the use of Protected Material at trial.

5. **DURATION**

Even after the termination of these cases, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

6. **ACCESS TO AND USE OF PROTECTED MATERIAL**

(a) **Basic Principles.** All Protected Material shall be used solely for these cases or any related appellate proceedings, and not for any other purpose whatsoever, including without limitation, any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed, or made available to anyone except as expressly provided in this Order.

(b) **Patent Prosecution Bar.** After the adoption of this provision by the parties, Outside Counsel and any person associated with a Party who receives a Producing Party's material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order or who has access to, accesses, or otherwise learns of, in whole or in part, said material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order shall not prepare, prosecute, supervise, advise, counsel, or assist in the preparation or prosecution of any patent application seeking a patent on behalf of the Receiving Party or its acquirer, successor, predecessor, or Affiliate in the field of non-invasive monitoring and/or consumer wearables (generally or as

described in any patent in suit) during the pendency of this Action and for two years after final termination of this action, including all appeals. To avoid any doubt, “prosecution” as used in this section does not include representing or advising a Party before a domestic or foreign agency in connection with a reissue, ex parte reexamination, covered business method review, inter partes review, opposition, cancellation, or similar proceeding; though in connection with any such foreign or domestic agency proceeding involving the patents-in-suit, any attorney who has access to, accesses, obtains, receives, or otherwise learns, in whole or in part, any other Party’s “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” shall not: (i) participate in the preparation, prosecution, supervision, advice, counsel, or assistance of any amended claims; (ii) reveal a Producing Party’s Protected Material to any prosecuting reexamination counsel or agent; or (iii) use a Producing Party’s Protected Material for any purpose not permitted by Section 1.

(c) Secure Storage, No Export. Protected Material must be stored and maintained by a Receiving Party at a location in the United States and in a secure manner that ensures that access is limited to the persons authorized under this Order. To ensure compliance with applicable United States Export Administration Regulations, Protected Material may not be exported outside the United States or released to any foreign national, even if within the United States. This applies to such information regardless of whether it is in the form of a stand-alone document or as an exhibit, attachment, or appendix to anything, including but not limited to briefs, reports, letters to counsel, discovery responses, or court filings—whether drafts or final versions. Foreign nationals shall not include the Parties’ Outside Counsel who reside in the United States, agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A, and who are identified in writing to the Producing Party. However, the Parties’ Outside Counsel

may access briefs, reports, letters to counsel, discovery responses, and court filings (including drafts) that contain Protected Material for purposes of working on these cases while traveling temporarily outside the United States, exclusive of any exhibits or appendices that attach or substantially reproduce or summarize documents, data, or testimony that have been designated by any other party as Protected Material. The Parties will use their best efforts to minimize the amount of Protected Materials in those documents (including without limitation by redacting references to Protected Materials that are not necessary for the work performed outside of the United States) to help ensure the security of the Parties' Protected Materials. Also, if this case eventually requires depositions or experts located outside the United States, the parties will revisit this issue and attempt to agree about exporting specific materials to the extent necessary. The Parties agree that neither Party waives the right to seek amendment of this Protective Order by the Court, following a meet and confer, if other circumstances concerning exportation arise in this case.

(d) Legal Advice Based on Protected Material. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to these cases based in whole or in part upon Protected Materials, provided counsel does not disclose the Protected Material itself except as provided in this Order.

(e) Limitations. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an

obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

7. **DESIGNATING PROTECTED MATERIAL**

(a) Available Designations. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE.”

(b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include “electronically stored information,” as that phrase is used in Federal Rule of Procedure 34), and tangible things that meet the requirements for the confidentiality designations listed in Section 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” during the inspection and re-designated, as appropriate during the copying process.

(c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL - OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE,” material, or

shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to an expert or consultant pre-approved pursuant to Section 12, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the designation of the Producing Party and including the production number and designation associated with the native file. The parties reserve the right to object to the use of any image format version of a document produced in native format to the extent any information has been altered.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given or by sending written notice of how portions of the transcript of the testimony are designated within fifteen (15) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” until the time within which it may be appropriately designated as provided for herein has passed. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of “This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative

Protective Order in this matter or pursuant to written stipulation of the parties.” Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent’s counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

8. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL” if it contains or reflects confidential, proprietary, and/or commercially sensitive information.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL” may be disclosed only to the following:

(i) The Receiving Party’s Outside Counsel, such counsel’s immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this case, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(iii) Any outside expert or consultant retained by the Receiving Party to assist in these cases, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current

officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (d) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iv) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is an employee of the Producing Party, or identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from metadata, cover emails, or other records of distribution) that the witness has seen or had access to the document previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(v) Court reporters, stenographers and videographers retained to record testimony taken in these cases, and their staff;

(vi) The Court, jury, and court personnel;

(vii) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(viii) Mock jurors having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A.

(ix) Any mediator who is assigned to hear these matters, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(x) Any other person with the prior written consent of the Producing Party.

9. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL – ATTORNEYS’ EYES ONLY”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if non-public, shall be presumed to merit the “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, engineering documents, testing documents, employee information, and other non-public information of similar competitive and business sensitivity.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may be disclosed only to:

(i) The Receiving Party’s Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such

Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from testimony, metadata, cover emails, or other records of distribution) that the witness has previously seen or had access to the document or the information contained therein; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that

the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vii) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(viii) Any other person with the prior written consent of the Producing Party.

(c) In addition, a Party may disclose arguments and materials derived from Discovery Material designated as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” to mock jurors who have signed an undertaking or agreement agreeing not to publicly disclose Protected Material and to keep any information concerning Protected Material confidential. A Party may not disclose to mock jurors any original, as-produced materials or information (including, for example, documents, deposition testimony, or interrogatory responses) produced by another Party designated as “CONFIDENTIAL - ATTORNEYS’ EYES ONLY.”

10. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE”**

(a) To the extent production of Source Code becomes necessary to the prosecution or defense of the cases, a Producing Party may designate Source Code as

“CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE” if it comprises or includes confidential, proprietary, and/or trade secret Source Code.

(b) Nothing in this Order shall be construed as a representation or admission that Source Code is properly discoverable in these cases, or to obligate any Party to produce any Source Code.

(c) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE” shall be subject to the provisions set forth in Section 11 below, and may be disclosed, subject to Section 11 below, solely to:

(i) The Receiving Party’s Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such Outside Counsel’s immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not

transport them to or access them from any foreign jurisdiction; and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the material as an author, addressee, or recipient of the material, or if there are indicia (such as from testimony, metadata, emails, or other records of distribution) that the witness has seen or had access to the materials previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(vii) Any other person with the prior written consent of the Producing Party.

11. **DISCLOSURE AND REVIEW OF SOURCE CODE**

(a) Any Source Code that is produced by Plaintiff will be made available for inspection at the San Francisco office of its outside counsel, Desmarais LLP, or any other location mutually agreed by the Parties. Any Source Code that is produced by Masimo will be made

available for inspection at the Orange County office of their outside counsel, Knobbe Martens Olsen & Bear LLP, or any other location mutually agreed by the Parties. Source Code will be made available for inspection between the hours of 8 a.m. and 6 p.m. on business days (i.e., weekdays that are not Federal holidays), although the Parties will be reasonable in accommodating reasonable requests to conduct inspections at other times.

(b) Prior to the first inspection of any requested Source Code, the Receiving Party shall provide ten (10) days' notice of its intent to review the Source Code that has been made available by the Producing Party and, if known, the specific Source Code the Receiving Party intends to inspect. The Receiving Party shall provide seven (7) days' notice prior to any additional inspections.

(c) Source Code that is designated "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be produced for inspection and review subject to the following provisions, unless otherwise agreed by the Producing Party:

(i) All Source Code shall be made available by the Producing Party to the Receiving Party's Outside Counsel and/or experts in a secure room on a secured computer without Internet access or network access to other computers and on which all access ports have been disabled (except for one printer port), as necessary and appropriate to prevent and protect against any unauthorized copying, transmission, removal or other transfer of any Source Code outside or away from the computer on which the Source Code is provided for inspection (the "Source Code Computer" in the "Source Code Review Room"). The Producing Party shall install tools that are sufficient for viewing and searching the code produced, on the platform produced, if such tools exist and are presently used in the ordinary course of the Producing Party's business. The Receiving Party's Outside Counsel and/or experts may request that commercially available

software tools for viewing and searching Source Code be installed on the secured computer, provided, however, that (a) the Receiving Party possesses an appropriate license to such software tools; (b) the Producing Party approves such software tools (approvals will not be unreasonably denied); and (c) such other software tools are reasonably necessary for the Receiving Party to perform its review of the Source Code consistent with all of the protections herein. The Receiving Party must provide the Producing Party with the CD or DVD or other media containing such licensed software tool(s) at least seven (7) days in advance of the date upon which the Receiving Party wishes to have the additional software tools available for use on the Source Code Computer.

(ii) No recordable media or recordable devices, including without limitation sound recorders, computers, cellular telephones, peripheral equipment, cameras, CDs, DVDs, or drives of any kind, shall be permitted into the Source Code Review Room.

(iii) The Receiving Party's Outside Counsel and/or experts shall be entitled to take notes relating to the Source Code but may not copy the Source Code into the notes and may not take such notes electronically on the Source Code Computer itself or any other computer.

(iv) The Producing Party may visually monitor the activities of the Receiving Party's representatives during any Source Code review, but only to ensure that no unauthorized electronic records of the Source Code and no information concerning the Source Code are being created or transmitted in any way.

(v) No copies of all or any portion of the Source Code may leave the room in which the Source Code is inspected except as otherwise provided herein. Further, no other written or electronic record of the Source Code is permitted except as otherwise provided herein. The Producing Party shall make available a laser printer with commercially reasonable

printing speeds for on-site printing during inspection of the Source Code. The Receiving Party may print limited portions of the Source Code only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). The Receiving Party may print the Source Code in 12-point font and with information necessary to later identify that Source Code, such as, but not limited to, a header or footer, that identifies the file name and directory path. Any printed portion that consists of more than fifteen (15) pages of a continuous block of Source Code shall be presumed to be excessive, and the burden shall be on the Receiving Party to demonstrate the need for such a printed copy. The Receiving Party may print out no more than 200 pages total without prior agreement from the Producing Party or order of the Court. The Receiving Party shall not print Source Code in order to review blocks of Source Code elsewhere in the first instance, i.e., as an alternative to reviewing that Source Code electronically on the Source Code Computer, as the Parties acknowledge and agree that the purpose of the protections herein would be frustrated by printing portions of code for review and analysis elsewhere, and that printing is permitted only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). Upon printing any such portions of Source Code, the printed pages shall be collected by the Producing Party. The Producing Party shall Bates number, copy, and label "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" any pages printed by the Receiving Party. Within seven (7) days, the Producing Party shall either (i) provide one copy set of such pages to the Receiving Party or (ii) inform the Requesting Party that it objects that the printed portions are excessive and/or not done for a permitted purpose. If, after meeting and conferring, the Producing Party and the Receiving Party cannot resolve the objection, the Receiving Party shall be entitled to seek a Court resolution of whether the printed Source Code in question is narrowly tailored and was printed for a permitted purpose. The

burden shall be on the Receiving Party to demonstrate that such printed portions are no more than is reasonably necessary for a permitted purpose and not merely printed for the purposes of review and analysis elsewhere. The printed pages shall constitute part of the Source Code produced by the Producing Party in these cases.

(vi) All persons who will review a Producing Party's Source Code on behalf of a Receiving Party, including members of a Receiving Party's outside law firm, shall be identified in writing to the Producing Party at least five (5) days in advance of the first time that such person reviews such Source Code. Such identification shall be in addition to any other disclosure required under this Order. All persons viewing Source Code shall sign on each day they view Source Code a log that will include the names of persons who enter the locked room to view the Source Code and when they enter and depart. The Producing Party shall be entitled to a copy of the log upon one (1) day's advance notice to the Receiving Party.

(vii) Unless otherwise agreed in advance by the Parties in writing, following each day on which inspection is done under this Order, the Receiving Party's Outside Counsel and/or experts shall remove all notes, documents, and all other materials from the Source Code Review Room. The Producing Party shall not be responsible for any items left in the room following each inspection session, and the Receiving Party shall have no expectation of confidentiality for any items left in the room following each inspection session without a prior agreement to that effect. Proper identification of all authorized persons shall be provided prior to any access to the secure room or the computer containing Source Code. Proper identification requires showing, at a minimum, a photo identification card sanctioned by the government of any State of the United States, by the government of the United States, or by the nation state of the authorized person's current citizenship. Access to the secure room or the Source Code Computer

may be denied, at the discretion of the supplier, to any individual who fails to provide proper identification.

(viii) Other than as provided above, the Receiving Party will not copy, remove, or otherwise transfer any Source Code from the Source Code Computer including, without limitation, copying, removing, or transferring the Source Code onto any recordable media or recordable device. The Receiving Party will not transmit any Source Code in any way from the Producing Party's facilities or the offices of its Outside Counsel of record.

(ix) The Receiving Party's Outside Counsel of record may make no more than three (3) additional paper copies of any portions of the Source Code received from a Producing Party pursuant to Section 11(c)(v), not including copies attached to court filings or used at depositions, and shall maintain a log of all paper copies of the Source Code. The log shall include the names of the reviewers and/or recipients of paper copies and locations where the paper copies are stored. Upon one (1) day's advance notice to the Receiving Party by the Producing Party, the Receiving Party shall provide a copy of this log to the Producing Party.

(x) The Receiving Party's Outside Counsel of record and any person receiving a copy of any Source Code shall maintain and store any paper copies of the Source Code at their offices in a manner that prevents duplication of or unauthorized access to the Source Code, including, without limitation, storing the Source Code in a locked room or cabinet at all times when it is not in use. No more than a total of fifteen (15) individuals identified by the Receiving Party shall have access to the printed portions of Source Code (except insofar as such code appears in any court filing or expert report).

(xi) For depositions, the Receiving Party shall not bring copies of any printed Source Code. Rather, at least seven (7) days before the date of the deposition, the Receiving

Party shall notify the Producing Party about the specific portions of Source Code it wishes to use at the deposition, and the Producing Party shall bring printed copies of those portions to the deposition for use by the Receiving Party. The Producing Party shall also accommodate reasonable requests from the Receiving Party to make a Source Code Computer available at the deposition for use at the deposition. Copies of Source Code that are marked as deposition exhibits shall not be provided to the Court Reporter or attached to deposition transcripts; rather, the deposition record will identify the exhibit by its production numbers. All paper copies of Source Code brought to the deposition shall remain with the Producing Counsel's Outside Counsel for secure destruction in a timely manner following the deposition.

(xii) Except as provided in this section, absent express written permission from the Producing Party, the Receiving Party may not create electronic images, or any other images, or make electronic copies, of the Source Code from any paper copy of Source Code for use in any manner (including by way of example only, the Receiving Party may not scan the Source Code to a PDF or photograph the code). Images or copies of Source Code shall not be included in correspondence between the Parties (references to production numbers shall be used instead), and shall be omitted from pleadings and other papers whenever possible. If a Party reasonably believes that it needs to submit a portion of Source Code as part of a filing with the Court, the Parties shall meet and confer as to how to make such a filing while protecting the confidentiality of the Source Code and such Source Code will not be filed absent agreement from the Producing Party that the confidentiality protections will be adequate. If a Producing Party agrees to produce an electronic copy of all or any portion of its Source Code or provide written permission to the Receiving Party that an electronic or any other copy needs to be made for a Court filing, access to the Receiving Party's submission, communication, and/or disclosure of electronic files or other materials

containing any portion of Source Code (paper or electronic) shall at all times be limited solely to individuals who are expressly authorized to view Source Code under the provisions of this Order. Where the Producing Party has provided the express written permission required under this provision for a Receiving Party to create electronic copies of Source Code, the Receiving Party shall maintain a log of all such electronic copies of any portion of Source Code in its possession or in the possession of its retained consultants, including the names of the reviewers and/or recipients of any such electronic copies, and the locations and manner in which the electronic copies are stored. Additionally, any such electronic copies must be labeled “CONFIDENTIAL - ATTORNEYS’ EYES ONLY - SOURCE CODE” as provided for in this Order.

12. **NOTICE OF DISCLOSURE**

(a) Prior to disclosing any Protected Material to any person described in Sections 8(b)(iii), 9(b)(ii), or 10(c)(ii) (referenced below as “Person”), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:

- (i) the name of the Person;
- (ii) an up-to-date curriculum vitae of the Person;
- (iii) the present employer and title of the Person;
- (iv) an identification of all of the Person’s past and current employment and consulting relationships in the past five years, including direct relationships and relationships through entities owned or controlled by the Person, including but not limited to an identification of any individual or entity with or for whom the person is employed or to whom the person provides consulting services relating to the design, development, operation, or patenting of technologies relating to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit), or relating to the acquisition of intellectual property assets relating

to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit);

(v) an identification of all pending patent applications on which the Person is named as an inventor, in which the Person has any ownership interest, or as to which the Person has had or anticipates in the future any involvement in advising on, consulting on, preparing, prosecuting, drafting, editing, amending, or otherwise affecting the scope of the claims; and

(vi) a list of the cases in which the Person has testified at deposition or trial within the last five (5) years.

Further, the Party seeking to disclose Protected Material shall provide such other information regarding the Person's professional activities reasonably requested by the Producing Party for it to evaluate whether good cause exists to object to the disclosure of Protected Material to the outside expert or consultant.

(b) Within ten (10) days of receipt of the disclosure of the Person, the Producing Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the ten (10) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this ten (10) day period. If the Producing Party objects to disclosure to the Person within such ten (10) day period, the Parties shall meet and confer via telephone or in person within four (4) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have four (4) days from the date of the meet and confer to seek relief from the Court and shall have the burden of proving the need for a protective order. If relief is not sought from the Court within that time, the objection

shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

(c) For purposes of this section, “good cause” shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Material in a way or ways that are inconsistent with the provisions contained in this Order.

(d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the “Agreement to Be Bound by Protective Order” (Exhibit A hereto) and serve it on all Parties.

(e) An initial failure to object to a Person under this Section 12 shall not preclude the nonobjecting Party from later objecting to continued access by that Person for good cause. If an objection is made, the Parties shall meet and confer via telephone or in person within seven (7) days following the objection and attempt in good faith to resolve the dispute informally. If the dispute is not resolved, the Party objecting to the disclosure will have seven (7) days from the date of the meet and confer to seek relief from the Court. The designated Person may continue to have access to information that was provided to such Person prior to the date of the objection. If a later objection is made, no further Protected Material shall be disclosed to the Person until the Court resolves the matter or the Producing Party withdraws its objection. Notwithstanding the foregoing, if the Producing Party fails to move for a protective order within seven (7) business days after the meet and confer, further Protected Material may thereafter be provided to the Person.

13. **CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL**

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

(b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:

(i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;

(ii) Failing agreement, the Receiving Party may bring a request or motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;

(iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

14. **DATA SECURITY**

(a) The Receiving Party shall implement an information security management system ("ISMS") to safeguard Protected Materials, including reasonable and appropriate

administrative, physical, and technical safeguards, and network security and encryption technologies governed by written policies and procedures, which shall comply with at least one of the following standards: (a) the International Organization for Standardization's 27001 standard; (b) the National Institute of Standards and Technology's (NIST) 800-53 standard; (c) the Center for Internet Security's Critical Security Controls, Version 8; or (d) the most recently published version of another widely recognized industry or government cybersecurity framework. The Parties shall implement encryption of all Protected Materials in transit outside of network(s) covered by the Party's ISMS (and at rest, where reasonably practical). Moreover, the Parties agree not to access Protected Materials from public computers.

(b) If the Receiving Party becomes aware of any unauthorized access, use, or disclosure of Protected Materials or devices containing Protected Materials ("Data Breach"), the Receiving Party shall promptly, and in no case later than 48 hours after learning of the Data Breach, notify the Producing Party in writing and fully cooperate with the Producing Party as may be reasonably necessary to (a) determine the source, extent, or methodology of such Data Breach, (b) recover or protect Protected Materials, and/or (c) to satisfy the Producing Party's legal, contractual, or other obligations. For the avoidance of doubt, notification obligations under this section arise when the Receiving Party both (a) learns of a Data Breach, and (b) learns that any of the Producing Party's Protected Materials are potentially subject to the Data Breach. The notification obligations set forth in this section do not run from the time the Data Breach itself.

(c) If the Receiving Party is aware of a Data Breach, the Parties shall meet and confer in good faith regarding any adjustments that should be made to the discovery process and discovery schedule in these cases, potentially including but not limited to (1) additional security measures to protect Discovery Material; (2) a stay or extension of discovery pending investigation

of a Data Breach and/or implementation of additional security measures; and (3) a sworn assurance that Discovery Material will be handled in the future only by entities not impacted by the Data Breach. In the event of a Data Breach affecting Protected Material of the Designating Party, at the Designating Party's request, the Receiving Party within 10 business days shall provide a copy of its most recent ISMS policies and procedures that relate to the safeguarding of Protected Materials and that preceded the Data Breach. Further, the Receiving Party shall submit to reasonable discovery concerning the Data Breach.

15. **SUBPOENAS OR COURT ORDERS**

(a) If at any time Protected Material is subpoenaed by any court, arbitral, administrative, or legislative body, the Party to whom the subpoena or other request is directed shall immediately give prompt written notice thereof to every Party who has produced such Discovery Material and to its counsel and shall provide each such Party with an opportunity to move for a protective order regarding the production of Protected Materials implicated by the subpoena. The Producing Party must also notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order, and include a copy of this Protective Order. The parties agree to work together to allow the Producing Party to seek a protective order, after the filing of which the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL – ATTORNEYS EYES ONLY" or "CONFIDENTIAL – ATTORNEYS EYES ONLY – SOURCE CODE" before a determination on the protective order by the court from which the subpoena or order issued, unless the Party has obtained the Producing Party's permission.

16. **FILING PROTECTED MATERIAL**

(a) Absent written permission from the Producing Party or a court Order secured after appropriate notice to all interested persons, a Receiving Party may not file or disclose in the public record any Protected Material.

(b) Any Party is authorized under District of Delaware Local Rule 5.1.3 to file under seal with the Court any brief, document or materials that are designated as Protected Material under this Order. However, nothing in this section shall in any way limit or detract from this Order's requirements as to Source Code.

17. **INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL**

(a) Pursuant to Federal Rule of Evidence 502(d) and (e), the inadvertent production by a Party of Discovery Material subject to the attorney-client privilege, work-product protection, or any other applicable privilege or protection, despite the Producing Party's reasonable efforts to prescreen such Discovery Material prior to production, will not waive the applicable privilege and/or protection in any other federal or state proceeding if a request for return of such inadvertently produced Discovery Material is made promptly after the Producing Party learns of its inadvertent production. For example, the mere production of a privileged or work product protected document in this case as part of a production is not itself a waiver. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI. Moreover, nothing in this Order shall be interpreted to require disclosure of information subject to privacy protections as set forth in law or

regulation, including information that may need to be produced from outside of the United States and/or may be subject to foreign laws.

(b) Upon a request from any Producing Party who has inadvertently produced Discovery Material that it believes is privileged and/or protected, each Receiving Party shall immediately return such Protected Material or Discovery Material and all copies to the Producing Party, except for any pages containing privileged markings by the Receiving Party which shall instead be destroyed and certified as such by the Receiving Party to the Producing Party.

(c) Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, addresses, and topic of the inadvertently produced Discovery Material and such other information as is reasonably necessary to identify the Discovery Material and describe its nature to the Court in any motion to compel production of the Discovery Material.

18. **INADVERTENT FAILURE TO DESIGNATE PROPERLY**

(a) The inadvertent failure by a Producing Party to designate Discovery Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within ten (10) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce the Protected Material with the correct confidentiality designation within five (5) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.

(b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material

is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material (subject to the exception in Section 18(c) below) at the appropriately designated level pursuant to the terms of this Order.

(c) Notwithstanding the above, a subsequent designation of “CONFIDENTIAL,” “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” shall apply on a going forward basis and shall not disqualify anyone who reviewed “CONFIDENTIAL,” “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” materials while the materials were not marked “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” from engaging in the activities set forth in Section 6(b).

19. **INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER**

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected.

20. **FINAL DISPOSITION**

(a) Not later than ninety (90) days after the Final Disposition of these cases, each Party shall return all Discovery Material of a Producing Party to the respective Outside Counsel of the Producing Party or destroy such Material, at the option of the Producing Party. For purposes of this Order, “Final Disposition” occurs after an order, mandate, or dismissal finally terminating these cases with prejudice, including all appeals.

(b) All Parties that have received any such Discovery Material shall certify in writing that all such materials have been returned to the respective Outside Counsel of the Producing Party or destroyed. Notwithstanding the provisions for return of Discovery Material, Outside Counsel may retain one set of pleadings, correspondence and attorney and consultant work product (but not document productions) for archival purposes, but must return any pleadings, correspondence, and consultant work product that contain Source Code.

21. **MISCELLANEOUS**

(a) **Right to Further Relief.** Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.

(b) **Termination of Matters and Retention of Jurisdiction.** The Parties agree that the terms of this Protective Order shall survive and remain in effect after the Final Determination of the above-captioned matters. The Court shall retain jurisdiction after Final Determination of these matters to hear and resolve any disputes arising out of this Protective Order.

(c) Successors. This Order shall be binding upon the Parties hereto, their successors, and anyone, including law firms, who obtains access to Protected Material.

(d) Right to Assert Other Objections. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in these cases or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in these cases or any other proceeding.

(e) Modification by Court. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material, however designated, produced under the protection of this Order shall be resolved by the United States District Court for the District of Delaware.

POTTER ANDERSON & CORROON LLP

PHILLIPS MCLAUGHLIN & HALL, P.A.

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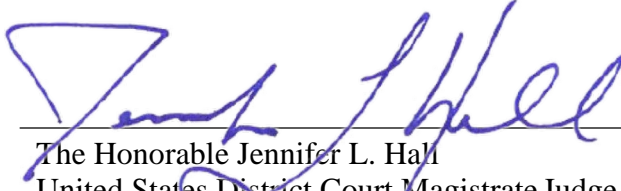
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*Attorneys for Defendants Masimo Corporation
and Sound United, LLC*

Attorneys for Plaintiff Apple Inc.

Dated: June 14, 2023

IT IS SO ORDERED this 16th day of June, 2023.



The Honorable Jennifer L. Hall
United States District Court Magistrate Judge

EXHIBIT A

I, _____, acknowledge and declare that I have received a copy of the Protective Order (“Order”) in *Apple Inc. v. Masimo Corp. et al.*, United States District Court, District of Delaware, C.A. Nos. 22-1377-MN-JLH and 22-1378-MN-JLH. Having read and understood the terms of the Order, I agree to be bound by the terms of the Order and consent to the jurisdiction of said Court for the purpose of any proceeding to enforce the terms of the Order.

Name of individual: _____

Present occupation/job description: _____

Name of Company or Firm: _____

Address: _____

Dated: _____

[Signature]

10869538

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APPLE INC.,

Plaintiff,

v.

MASIMO CORPORATION and
SOUND UNITED, LLC,

Defendants.

C.A. No. 22-1377-MN-JLH

C.A. No. 22-1378-MN-JLH

JURY TRIAL DEMANDED

MASIMO CORPORATION and
CERCACOR LABORATORIES, INC.,

Counter-Claimants,

v.

APPLE INC.

Counter-Defendant.

**PLAINTIFF APPLE INC.'S FIRST SUPPLEMENTAL OBJECTIONS AND
RESPONSES TO DEFENDANTS' AND COUNTERCLAIMANTS'
THIRD SET OF INTERROGATORIES (NO. 23)**

Pursuant to Rules 26 and 33 of the of the Federal Rules of Civil Procedure, Plaintiff Apple Inc. ("Apple") hereby supplements its response to Defendant and Counterclaimant Masimo Corporation's ("Masimo"), Defendant Sound United, LLC's ("Sound United"), and Counterclaimant Cercacor Laboratories, Inc.'s ("Cercacor") (jointly, "Defendants and Counterclaimants") Third Set of Interrogatories to Apple (No. 23). Apple's discovery and investigation in connection with this action are continuing. As a result, Apple's objections and responses are limited to information obtained and reviewed to date and are given without prejudice

to Apple's right to supplement or amend these objections and responses to the extent allowed by the Federal Rules of Civil Procedure, the Local Rules of this Court, and any applicable scheduling orders as discovery and Apple's investigation in the action proceeds. Apple hereby incorporates the general objections set forth in Apple's Response to Defendants' Third Set of Interrogatories (Nos. 19-23), which Apple served on July 5, 2023.

GENERAL OBJECTIONS

Apple makes the following General Objections to Defendants' and Counterclaimants' Third Set of Interrogatories, which apply to each interrogatory regardless of whether the General Objections are specifically incorporated into the specific objections and responses below. Apple incorporates by reference the General Objections set forth in its Objections and Responses to Defendants' Second Set of Interrogatories, which apply to each request regardless of whether the General Objections are specifically incorporated into the specific objections and responses below. Apple further objects as follows:

1. Apple objects to each interrogatory, definition, and instruction as overbroad, unduly burdensome, and calling for information that is neither relevant to any party's claim or defense, nor proportional to the needs of the case. Specifically, Apple objects to each request to the extent it seeks discovery (1) not specific to any product relevant to this matter and/or (2) regarding acts (*e.g.*, making, using, selling, and offering for sale, of any product) outside of the United States. To the extent Defendants and Counterclaimants request discovery not specific to a relevant product and/or outside of the United States, each such request is overbroad, unduly burdensome, and irrelevant as calling for discovery outside the relevant temporal or geographic scope of this matter.
2. Apple objects to each interrogatory as overbroad, unduly burdensome, and calling for information that is neither relevant to any party's claim or defense, nor proportional to the

needs of the case, to the extent it calls for information beyond any other temporal limitations of this case. To the extent Masimo requests discovery for purposes of its patent infringement counterclaims, pursuant to 35 U.S.C. § 286, “no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint . . . for infringement in the action.” Counterclaimants filed their counterclaims in this action on December 12, 2022, so Counterclaimants cannot recover for any alleged infringement prior to December 12, 2016. To the extent Masimo requests discovery prior to December 12, 2016, each such request is overbroad, unduly burdensome, and irrelevant to the extent it calls for discovery outside the relevant temporal scope of this case. Furthermore, to the extent Masimo requests discovery for purposes of its antitrust, false advertising, and/or unfair competition counterclaims (Counterclaims I through VI), Apple objects to any request for discovery prior to December 12, 2020, on the grounds that such request is overbroad, unduly burdensome, and irrelevant to the extent it calls for discovery outside the relevant temporal scope of this case.

3. Apple’s willingness to provide any document or information in response to an interrogatory shall not be interpreted as an admission that such document or information exists, that it is relevant to a claim or defense in this action, or that it is admissible for any purpose. Apple does not waive its right to object to the admissibility of any document or information produced by any party on any ground.

OBJECTIONS AND RESPONSES

INTERROGATORY NO. 23:

To the extent not already identified in Your response to Masimo’s Interrogatory Nos. 17-19, identify all of Your defenses to Masimo’s claims in its Counterclaims at the same level of detail that will be required when you file your Answer to Masimo’s Counterclaims.

RESPONSE TO INTERROGATORY NO. 23:

Apple incorporates by reference its General Objections. In addition, Apple further objects to this interrogatory as premature to the extent it calls for a recitation of affirmative defenses before Apple's answer to the Counterclaims is due, and before any final ruling on Apple's pending motions to dismiss. To the extent the interrogatory seeks identification of "defenses" beside the affirmative defenses that would be listed in Apple's answer to the Counterclaims, Apple objects on the grounds that the request is unduly burdensome and overly broad. In addition, the request would be vague in that Apple is not in a position to rebut arguments and evidence Counterclaimants have not yet advanced. Such a request is premature before the completion of fact and expert discovery. Apple further objects to this interrogatory as premature to the extent it calls for information in advance of the disclosure timeline required by the Federal Rules.

Based on its investigation to date, and subject to and without waiver of the forgoing general and specific objections, and to the extent that this interrogatory can be understood, Apple responds as follows:

Apple incorporates by reference its responses to Interrogatories Nos. 17-22 as if fully set forth herein.

Each counterclaim fails to state a claim upon which relief can be granted.

Each counterclaim fails because Counterclaimants cannot meet their burden of proof with respect to one or more essential elements, either because of failure of proof, or estoppel, or both.

Counterclaimants lack standing to assert each counterclaim due to lack of injury-in-fact.

Masimo lacks standing to assert its counterclaims under the Sherman Act (Counterclaims I and II) for lack of antitrust injury.

To the extent they arise from Apple's assertion of patent claims against Masimo, Masimo's claims under the Sherman Act and California UCL (Counterclaim VI) are barred by the Noerr-Pennington doctrine and all other immunities provided by the First Amendment and by the United States patent laws.

To the extent they arise from Apple's review of and approval of any app for the Apple App Store, Masimo's claims under the Sherman Act and California UCL are barred because Apple does not have an antitrust duty to deal, and in any event, would fail because Apple's alleged conduct is supported by valid business justifications, including without limitation Apple's interest in ensuring that apps meet quality, reliability, and consumer protection standards. Furthermore, Masimo cannot establish any of Apple's conduct harmed Masimo or Cercacor, given that the Masimo and Cercacor apps are currently available on the app store, and during a hearing on June 15, 2023, Masimo admitted that it never provided any confidential information to Apple as part of the App Store review.

To the extent they arise from any alleged misappropriation of Masimo's alleged trade secrets or alleged infringement or theft of any Masimo intellectual property or technology, Masimo's claims under the Sherman Act and California UCL are barred (1) because such conduct does not have the requisite exclusionary effect, and (2) by the doctrines of res judicata and claim splitting.

To the extent they arise from alleged false or misleading advertising, Masimo's claims under the Sherman Act and California UCL fail because the challenged advertising is supported by valid business justifications.

Masimo's counterclaim under the California UCL fails because it cannot show entitlement to any form of relief available under that law.

The counterclaims for patent infringement fail for the additional reason that Apple has not infringed and does not infringe any claim of the Masimo Asserted Patents, either directly or indirectly, literally or under the doctrine of equivalents.

The counterclaims for patent infringement fail for the additional reason that the claims of the Masimo Asserted Patents are invalid for failing to comply with one or more of the conditions for patentability as set forth in Title 35 of the United States Code, including without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

The counterclaims for patent infringement fail for the additional reason that Apple has not willfully infringed any of the Masimo Asserted Patents.

The counterclaims for patent infringement fail for the additional reason that the counterclaims are barred in whole or in part by the doctrine of waiver, acquiescence, estoppel, implied license, patent misuse, and/or unclean hands.

The counterclaims for patent infringement fail for the additional reason that Masimo's counterclaims are barred in whole or in part by the doctrine of prosecution laches.

The counterclaims for patent infringement fail for the additional reason that the Masimo Asserted Patents are unenforceable.

The counterclaims for patent infringement fail for the additional reason that the counterclaims are barred by 28 U.S.C. § 1498 to the extent that they relate to use or manufacture of the invention of the Masimo Asserted Patents by or for the United States.

The counterclaims for patent infringement fail for the additional reason that Counterclaimants are precluded from recovering any damages for any alleged infringement that occurred more than six years prior to the commencement of this counterclaim action.

The counterclaims for patent infringement fail for the additional reason that Counterclaimants are precluded from recovering damages, in whole or in part, by 35 U.S.C. § 287, due to a failure to mark by Counterclaimants and/or any predecessors in interest or any licensees to the Masimo Asserted Patents or failure to give proper notice that Apple's actions allegedly infringe the Asserted Patents. Counterclaimants' claims for relief are further barred, in whole or in part, under 35 U.S.C. § 288.

The counterclaims for patent infringement fail for the additional reason that the claims for injunctive relief are barred because Counterclaimants fail to meet the requirements for obtaining injunctive relief and by the doctrine of laches.

The counterclaims and Defendants' inequitable conduct defenses fail for at least the reasons set forth in Apple's briefing in support of its motions to dismiss (No. 22-1377, D.I. 54, 55, 88; No. 22-1378, D.I. 39, 40, 76).

Apple reserves the right to assert any additional defenses as they become known during the course of this action.

Apple will further respond to this interrogatory after it provides its answer to the Counterclaims in accordance with Rule 12(a) of the Federal Rules of Civil Procedure at which point Apple will plead its defenses to the counterclaims for patent infringement.

In addition to the foregoing, Apple reserves all affirmative defenses under Fed. R. Civ. P. 8(c) and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation.

The foregoing list shall not be construed as an admission by Apple that it bears the burden of proof on any aspect of these or any other defenses.

Apple reserves its right to supplement or amend its response to this interrogatory as discovery and its investigations in this action proceed in accordance with the Court's schedule.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 23 (AUGUST 2, 2023):

Apple hereby incorporates its July 5, 2023 objections and responses as if fully set forth herein. Based on its investigation to date, and subject to and without waiver of its general and specific objections, Apple further responds as follows:

The counterclaims for patent infringement fail for the additional reason that the Masimo Asserted Patents are unenforceable for inequitable conduct, as explained below:

Factual Background Regarding Individuals Who Committed Inequitable Conduct on Behalf of Masimo and Cercacor

Masimo is a litigious company that has inequitably obtained patents and attempted to sue its way to the top. Founded in 1989, Masimo has prosecuted scores of patents for assertion against competitors. As discussed in detail below and pertinent to this case, Masimo named inventors, such as Joe Kiani, and Masimo attorneys of record for prosecuting patents, such as Stephen Jensen, Harnik Shukla, and Jarom Kesler, committed inequitable conduct to deceive the USPTO into issuing the '223, '507, '743, '159, and '911 patents that Masimo now asserts against Apple in this case. These individuals committed inequitable conduct by, among other things, intentionally withholding material references and/or intentionally "burying" material references in voluminous information disclosure statements that contained hundreds of irrelevant citations. Indeed, Mr. Jensen—the same lawyer involved in the prosecution of and this litigation regarding the '223, '507, '743, '159, and '911—has been found by the Federal Circuit to have engaged in inequitable conduct in connection with a prior patent prosecution for Masimo. *See Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App'x 158 (Fed. Cir. 2005).

Masimo has repeatedly relied on patent litigation to expand its technological and economic footprint. For example, in the early 2000s, Masimo sued Nellcor Puritan Bennet, Inc. (“Nellcor”) for patent infringement with respect to Nellcor’s pulse oximeter products and used that lawsuit as leverage for a settlement that enabled Masimo to go public. Masimo subsequently sued Philips Electronics North America Corporation (“Philips”) for patent infringement and then used that lawsuit to leverage a settlement that forced Phillips to combine its products with those of Masimo. Overall, Masimo has commenced or otherwise been a party to over 15 patent infringement cases since 2000, including this instant case against Apple.

Masimo was founded by one of the named inventors of the ’223 patent, Joe Kiani. Since founding Masimo, Kiani has continuously served as its president, Chief Executive Officer, and Chairman of the Board—positions he holds to this day. Mr. Kiani also is president, CEO, and sits on the Board of Directors of Cercacor. As a putative inventor, CEO, and director of both Masimo and Cercacor, Kiani has actively monitored both the specific activities of its many competitors, including Nellcor, as well as broader technical advancements by others in the field of pulse oximetry. Mr. Kiani thus has deep knowledge of prior art as discussed further herein—knowledge that Masimo has nefariously exploited in prosecuting and litigating patents, including the patents asserted against Apple here.

Knobbe Martens is an intellectual property law firm that engages in both patent prosecution and patent litigation as part of its mantra of providing “complete patent services” in one law firm (<https://www.knobbe.com/services/practice-areas/patents>, last accessed August 2, 2023). For at least the past 25 years, Knobbe Martens has provided both patent prosecution and patent litigation services to Masimo. Since 1994, Knobbe Martens has prosecuted on Masimo’s behalf over 800 patent applications and litigated on Masimo’s behalf over 15 patent infringement cases, including

against Nellcor and Phillips. In many instances, the same Knobbe Martens attorneys that have been substantively involved in Masimo's patent litigations have also been substantively involved in Masimo's patent prosecutions, and vice versa.

Stephen Jensen is a partner at Knobbe Martens. Mr. Jensen has been a lawyer at Knobbe Martens since 1990 and a partner since 1994. Since 1994, Mr. Jensen has been Masimo's primary outside patent attorney, has continuously represented Masimo, and has served as Masimo's client liaison. Over the course of this period, Mr. Jensen has represented Masimo in both patent prosecutions and patent litigations. As Masimo's client liaison, Mr. Jensen has ultimate responsibility for and control over Knobbe Martens' legal work for Masimo.

Mr. Jensen has prosecuted numerous patent applications on Masimo's behalf. Mr. Jensen began prosecuting patents for Masimo starting around 1994. Today, the USPTO affirmatively lists Mr. Jensen as an attorney of record for prosecuting numerous Masimo patents, *including each of the patents that Masimo has asserted against Apple in this case.*

Mr. Jensen also has litigated numerous patents on Masimo's behalf and typically leads Masimo's litigation teams. Since Masimo's first patent litigation in 1999, Mr. Jensen has represented Masimo in at least the following patent litigations:

- *Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2-000cv06506 (C.D. Cal.)
- *Masimo Corp. v. Mallinckrodt Inc.*, Case Nos. 8-01-cv-00638 & 2-01-cv-07292 (C.D. Cal.);
- *Nellcor Puritan, et al. v. Masimo Corp.*, Case Nos. 8-02-cv-01133 & 2-03-cv-00603 (C.D. Cal.);
- *Masimo Corp. v. Jay*, Case No. 8-07-cv-01163 (C.D. Cal.);
- *Masimo Corp. v. Philips Electronics Northern America Corp.*, Case Nos. 1-09-cv-00080, 1-11-cv-00742, and 1-16-cv-00137 (D. Del.);

- *Hygia Health Services, Inc. v. Masimo Corp.*, Case No. 2-09-cv-00885 (N.D. Al.);
- *Essential Medical Devices, Inc. v. Masimo Corp.*, Case No. 1-11-cv-00734 (D. Del.);
- *Dominion Assets LLC v. Masimo Corp.*, Case Nos. 5-12-cv-02773, 5-14-cv-3002 (N.D. Cal.);
- *Masimo Corp. v. Mindray DS USA, Inc.*, Case Nos. 8-12-cv-02206 (C.D. Cal.), 2-15-cv-00457 (D.N.J.) and 2-15-cv-06900 (D.N.J.);
- *Masimo Corp. v. Shenzhen Mindray Bio-Medical Tech. Co.*, 12-cv-02206 (C.D. Cal.);
- *Masimo Corp. v. Nova Biomedical Corp.*, Jams International Arbitration, Reference No. 1220045324;
- *Christian Lewis v. Sheila D. Moore*, No. 15-13979 (11th Cir.), appeal from District Court No. 2:13-cv-00733-KOB;
- *Shandong Lihong Technology Limited Corp. v. Masimo Corp.*, Superior Court of the State of California, County of Orange, Case No. 30-2018-01002779-CU-BT-CJC;
- *Silkeen LLC v. Masimo Corp.*, C.A. No. 1:17-cv-01030-RGA (D. Del);
- *U.S. Ex. Rel Ruhe, Serwitz, and Catala v. Masimo Corp.*, 2:10-cv-08169-CJC-VBK (C.D. Cal);
- *Physicians Healthsource, Inc. et al. v. Masimo Corp.*, Case No. 8:14-cv-00001 JVS (ADSx) (C.D. Cal);
- *Masimo Corp. v. James Welch*, Case No. 30-2013-00659172 (Superior Ct. of Cal., Orange County);
- *Masimo Corp. v. Sotera Wireless, Inc.*, Case No. 3-19-cv-01100 (S.D. Cal.);
- *Masimo Corp. v. True Wearables, Inc.*, Case No. 8:18-cv-02001 (C.D. Cal.);
- *Masimo Corp. v. Apple, Inc.*, Case No. 8:20-cv-00048 (C.D. Cal.); and
- *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Case No. 337-TA-1276 (ITC).

Many of Masimo's patent infringement cases have included claims by and against Masimo's direct competitors concerning products that are material prior art to the patents that Masimo now asserted against Apple in this case. For example, one of Masimo's longstanding direct competitors has been Nellcor, which has sold prior art pulse oximeter products, including Nellcor NPB-195, N-395, and OxiMax N-595 products. Indeed, Mr. Jensen was Masimo's lead counsel in the litigation that Masimo filed against Nellcor as well as in the *inter partes* review proceedings that Masimo filed against Nellcor's patents.

Mr. Jensen is one of several Knobbe Martens attorneys who has litigated the same Masimo patents for which he has been an attorney of record for prosecution. As discussed further herein, Mr. Jensen has been listed by the USPTO as an attorney of record for at least the '223, '507, '743, '159, and '911 patents—the same patents that Masimo now asserts through Mr. Jensen and other Knobbe Martens lawyers against Apple in this case.

Mr. Jensen has publicly declared that “[n]o other lawyer at my firm has the same history and breadth of understanding of Masimo's and Cercacor's technology, their legal strategies, their principles and their legal goals.” Knobbe Martens publicizes that it and Masimo “have grown up together,” with Mr. Jensen playing significant roles in Masimo's development over time. (<https://www.law.com/therecorder/almID/1202724129923/>, last accessed August 2, 2023).

Masimo and Knobbe Martens' 30-year relationship, however, goes well beyond legal representation—it also extends to a series of intertwined business relationships in which commingling between Massimo and Knobbe Martens personnel has been the norm. For example, Mr. Jensen has personally worked in numerous in-house positions at Masimo itself, including as Masimo's Senior Vice President of OEM Business, Business Development, and General Counsel. In that capacity, Mr. Jensen has “directly managed Masimo's OEM business.”

(<https://www.knobbe.com/attorneys/steve-jensen>, last accessed August 2, 2023). Mr. Jensen is also one of four members of the Board of Directors of the Masimo Foundation for Ethics, Innovation and Competition in Healthcare.

Mr. Jensen also has intertwined, commingled relationships with Cercacor. Since 2013, Mr. Jensen has served (along with Joe Kiani) as one of the six directors on Cercacor's Board of Directors. In that capacity, Mr. Jensen has been deeply involved in Cercacor's highest levels of governance and owed an affirmative fiduciary duty to Cercacor. Indeed, Mr. Jensen's intertwined, commingled relationships with Masimo have been so extensive that the United States International Trade Commission recently required Mr. Jensen to resign his position as a member of Cercacor's Board of Directors as a condition for him to have access to Apple's confidential information in the parties' pending ITC case.

Through his work as a patent prosecutor and litigator on behalf of Masimo and Cercacor, as well as his senior in-house positions at Masimo and Cercacor themselves, Mr. Jensen has obtained deep knowledge of prior art, as discussed further herein. Mr. Jensen, however, has repeatedly elevated his loyalties to Masimo and Cercacor over his duties of disclosure to the USPTO through the commission of inequitable conduct. Indeed, Mr. Jensen has previously been found to have committed inequitable conduct at the Federal Circuit. *See, e.g., Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App'x 158 (Fed. Cir. 2005).

Harom Shukla and Jarom Kesler are partners of Mr. Jensen at Knobbe Martens who also are attorneys of record for prosecuting one or more of the patents that Masimo has asserted against Apple in this case. Like Mr. Jensen, both Mr. Shukla and Mr. Kesler had knowledge of prior art based on their work at Knobbe Martens doing patent prosecution and litigation work for Masimo.

As Masimo's primary outside patent attorney and client liaison, Mr. Jensen had ultimate responsibility for and control over Knobbe Martens' legal work for Masimo.

Masimo and Cercacor's claims of infringement for the '223 patent and the '507 patent are unenforceable due to inequitable conduct because the specific individuals identified above and below withheld from the USPTO prior art references that it knew were material to patentability with the specific intent to deceive the USPTO. Those individuals had extensive knowledge of these withheld references because they cited them in other parallel patent proceedings while withholding them from the USPTO in connection with the prosecutions of the '223 and '507 patents. This misconduct evidenced an intent to mislead and deceive the USPTO in order to improperly procure the '223 and '507 patents.

Masimo and Cercacor's claims of infringement for the '743 patent, the '159 patent, and the '911 patent are also unenforceable due to inequitable conduct because the specific individuals identified above and below repeatedly engaged in a pattern of burying highly material prior art among voluminous submissions of irrelevant and marginally relevant prior art with the specific intent to deceive the USPTO. Indeed, those individuals repeatedly buried material prior art references in Information Disclosure Statements that included over a thousand other references, including numerous clearly irrelevant references. This repeated pattern of misconduct evidenced an intent to mislead and deceive the USPTO in order to improperly procure the '743, '159 and '911 patents. *See, e.g., Pact XPP Schweiz AG v. Intel Corp.*, Case No. 1:19-cv-01006-JDW, 2023 WL 2631503 (D. Del. Mar. 23, 2023).

'223 Patent — Withholding of Material Prior Art

The '223 patent is unenforceable due to inequitable conduct occurring during its prosecution, including, among other misconduct, Joe Kiani and Stephen Jensen's withholding

from the USPTO of key prior art that each of those individuals knew was material to patentability. Kiani and Jensen had extensive knowledge of this prior art at the relevant time, as confirmed by the public record, including testimony, litigations, and publicly available documents. These actions constitute fraud through omission because they violated the duty of disclosure owed by each of those individuals to the USPTO. These actions were all done with a specific intent to deceive the USPTO, which would not have issued the '223 patent if it had been made properly aware of the withheld prior art.

As discussed below, Joe Kiani and Stephen Jensen are among the individuals who owed a duty of disclosure to the USPTO during the prosecution of the '223 patent and committed inequitable conduct by breaching that duty of disclosure.

Furthermore, Masimo and Knobbe Martens have an extensive 30-year relationship with overlapping members. For example, Jensen not only is a partner at Knobbe Martens, the law firm that prosecuted these patents, but also has served as Masimo's General Counsel and Senior Vice President of Original Equipment Manufacture (OEM) Business and Business Development and Jensen promotes himself as serving on the Board of Directors of Masimo affiliate Cercacor Corporation. (*See* <https://www.knobbe.com/attorneys/steve-jensen>, last accessed August 2, 2023). As another example, Jensen has been reported saying "I've represented [Masimo] since 1993 when they were a small group of engineers out of a very small office . . . I've represented them since almost the beginning." (*See* <https://www.ocbj.com/manufacturing/knobbe-partners-prep-for-masimo-case/>, last accessed August 2, 2023). Furthermore, Jensen and Knobbe Martens have been prosecuting Kiani and Masimo's patent applications since 1993 such that Masimo has "changed [Jensen's] personal and professional life immensely." (*See* <https://www.investors.com/news/management/leaders-and-success/masimo-ceo-four-guiding->

principles-turn-startup-success/, last accessed August 2, 2023). On information and belief, Kiani and others at Masimo selected the law firm Knobbe Martens to prosecute the '223 patent and other Masimo patents to exploit the 30-year commingled relationship that Masimo has with Knobbe Martens, which ensured total control over the prosecution process, including which material prior art to intentionally withhold from the USPTO to improperly obtain patents including the '223 patent.

Joe Kiani

Kiani is a named inventor on the '223 patent, a founder and Chief Executive Officer and Chairman of the Board of Masimo, and Chief Executive Officer and Chairman of the Board of Directors of Cercacor. Kiani had a duty to disclose information material to the patentability of the '223 patent to the USPTO during prosecution of the '223 patent at least because he is a named inventor on the '223 patent.

(12) United States Patent Al-Ali et al.	(10) Patent No.: US 8,190,223 B2 (45) Date of Patent: May 29, 2012
(54) NONINVASIVE MULTI-PARAMETER PATIENT MONITOR	<div> <div>4,157,708 A</div> <div>6/1979 Imura</div> </div> <div> <div>4,167,331 A</div> <div>9/1979 Nielsen</div> </div> <div> <div>4,266,554 A</div> <div>5/1981 Hamaguri</div> </div> <div> <div>4,267,844 A</div> <div>5/1981 Yamanishi</div> </div> <div> <div>4,446,871 A</div> <div>5/1984 Imura</div> </div> <div> <div>4,531,527 A</div> <div>7/1985 Reinhold, Jr. et al.</div> </div> <div> <div>4,586,513 A</div> <div>5/1986 Hamaguri</div> </div> <div> <div>4,621,643 A</div> <div>11/1986 Newet al.</div> </div>
(75) Inventors: Ammar Al-Ali , Tustin, CA (US); Joe Kiani , Laguna Niguel, CA (US); Mohamed Diab , Mission Viejo, CA (US); Greg Olsen , Irvine, CA (US); Roger Wu , Irvine, CA (US); Rick Fishel , Orange, CA (US)	(Continued)

('223 patent, cover page)

UTILITY APPLICATION	Attorney Docket No.: MLR.012A
	First Named Inventor: Ammar Al-Ali
	Title: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
	Express Mail Label No.: EV 307965144 US
Direct all correspondence to Customer No.: 20995	
	Date: March 1, 2006 Page 1

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

112935 U.S. PTO
11/367033
030106

The following enclosures are transmitted herewith to be filed in the patent application of:

INVENTORS LIST:

1. Ammar Al-Ali
2. Joe E. Kiani
3. Mohamed Diab
4. Greg Olsen
5. Roger Wu
6. Rick Fishel

(‘223 Patent Prosecution, March 1, 2006 Application).

Indeed, Kiani submitted a signed declaration of inventorship under oath and subject to a penalty of perjury in which he “acknowledge[d] the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56”:



DECLARATION - USA PATENT APPLICATION

I, a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled NONINVASIVE MULTI-PARAMETER PATIENT MONITOR; the specification of which was filed on March 1, 2006 as Application Serial No. 11/367,033.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56;

* * *

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

* * *

Full name of second inventor: Joe Kiani

Inventor's signature

Date

Residence: 35 Brindisi, Laguna Niguel, CA 92677

Citizenship: United States

Mailing Address: Same as above

('223 Patent Prosecution, June 15, 2006 Oath).

Stephen Jensen

Stephen Jensen had a duty to disclose information material to the patentability of the '223 patent to the USPTO during prosecution of the '223 patent. As a partner at the law firm of Knobbe Martens, Mr. Jensen was Masimo's primary outside counsel and an attorney of record for prosecution of the '223 patent who was substantively involved in the preparation and prosecution of the application that resulted in the '223 patent.

For example, the USPTO expressly lists Mr. Jensen as an attorney of record for prosecution of the '223 patent.

In addition to his own role as an attorney of record for prosecuting the '223 patent, Mr. Jensen—as Masimo's primary outside patent attorney and client liaison—was the Knobbe Martens partner who had ultimate responsibility for and control over Knobbe Martens' legal work for Masimo, including prosecution of the '223 patent. As such, Mr. Jensen had the incentive to, and

as discussed below did in fact, prioritize his longstanding loyalties to Masimo over his duties of disclosure to the PTO to facilitate issuance of the '223 patent by committing inequitable conduct.

During prosecution of the '223 patent, Masimo, including named inventor Kiani and its prosecution attorney of record and client liaison Jensen, as well as other Masimo agents substantively involved in the prosecution of the '223 patent, withheld from the USPTO known prior art that is material to the patentability of the '223 patent—including material information regarding the Nellcor NPB-195, N-395, and OxiMax N-595 patient monitors—with specific intent to deceive the USPTO.

The Nellcor NPB-195, N-395, and OxiMax N-595 are related products in Nellcor's line of patient monitors. For each patient monitor, Nellcor publicly released detailed documents describing the products' operation and functionality, such as Operator's Manuals. (*See* NPB-195 Operator's Manual, N-395 Operator's Manual, OxiMax N-595 Operator's Manual).

Each of the technical documents describing the Nellcor NPB-195, N-395, and OxiMax N-595 products is material prior art to the '223 patent and anticipates under 35 U.S.C. § 102 and/or renders obvious under 35 U.S.C. § 103, standing alone or combined with a person of ordinary skill in the art, at least claims 15, 21, 27, and 28 of the '223 patent, and otherwise contains disclosure material to the invalidity of the asserted claims of the '223 patent.

Particularly, the NPB-195 Operator's Manual describing the Nellcor NPB-195 is material prior art to the '223 patent, anticipates under 35 U.S.C. § 102 and/or renders obvious under 35 U.S.C. § 103, standing alone or combined with a person of ordinary skill in the art, at least claims 15, 21, 27, and 28 of the '223 patent, and otherwise contains disclosures material to the invalidity of the asserted claims of the '223 patent.

For example, claim 27 of the '223 patent requires “a user input button, the activation of which replaces the display of the measured value of the first blood parameter with the measured value of the second blood parameter,” where an amendment in this limitation led at least in part to the allowance of claim 27 of the '223 patent during reexamination. Under the apparent constructions advanced in Masimo’s infringement contentions, the NPB-195 Operator’s Manual teaches replacing the display of a pulse rate with a blood oxygen measurement value when a user input, such as a “softkey” button, is pressed. (*See* NPB-195 Operator’s Manual at 24, 29-30, 87-89). Moreover, the NPB-195 Operator’s Manual alone, under the apparent constructions advanced in Masimo’s infringement contentions, teaches every limitation of at least claims 15, 21, 27, and 28 of the '223 patent, and otherwise contains disclosures material to the invalidity of the asserted claims of the '223 patent.

Additionally, the OxiMax N-595 Operator’s Manual describing the Nellcor OxiMax N-595 is material prior art to the '223 patent, anticipate under 35 U.S.C. § 102 and/or render obvious under 35 U.S.C. § 103, standing alone or combined with a person of ordinary skill in the art, at least claims 15, 21, 27, and 28 of the '223 patent, and otherwise contains disclosures material to the invalidity of the asserted claims of the '223 patent.

For example, claim 27 of the '223 patent requires “a user input button, the activation of which replaces the display of the measured value of the first blood parameter with the measured value of the second blood parameter.” Under the apparent constructions advanced in Masimo’s infringement contentions, the OxiMax N-595 Operator’s Manual teaches replacing the display of a blood oxygen measurement value with a pulse rate when a user input, such as a “softkey” button, is pressed. (*See* OxiMax N-595 Operator’s Manual at 10-11, 32, 34-36, 80-86). Moreover, the OxiMax N-595 Operator’s Manual alone, under the apparent constructions advanced in Masimo’s

infringement contentions, teaches every limitation of at least claims 15, 21, 27, and 28 of the '223 patent, and otherwise contains disclosures material to the invalidity of the asserted claims of the '223 patent.

Additionally, the N-395 Operator's Manual describing the Nellcor N-395 is material prior art to the '223 patent and anticipates under 35 U.S.C. § 102 and/or renders obvious under 35 U.S.C. § 103, standing alone or combined with a person of ordinary skill in the art, at least claims 15, 21, 27, and 28 of the '223 patent, and otherwise contains disclosure material to the invalidity of the asserted claims of the '223 patent.

For example, claim 27 of the '223 patent requires "a user input button, the activation of which replaces the display of the measured value of the first blood parameter with the measured value of the second blood parameter." Under the apparent constructions advanced in Masimo's infringement contentions, and for the same reasons as those described above with respect to the NPB-195 Operator's Manual and the OxiMax N-595 Operator's Manual, the N-395 Operator's Manual teaches replacing the display of a blood oxygen measurement value with a pulse rate when a user input, such as a "softkey" button, is pressed. (*See* N-395 Operator's Manual at 30 (as seen with the NPB-195 and OxiMax N-595 Operator's Manuals, showing a Pleth View and a Blip View, where as an example under the apparent constructions advanced in Masimo's infringement contentions, the display of a blood oxygen measurement value in the Pleth View is replaced with a pulse rate in the Blip View), 31 (as seen with the NPB-195 and OxiMax N-595 Operator's Manuals, explaining that a user can select between the Pleth View and Blip View by pressing a softkey), 41, 44-45).

As such, the examiners for the '223 patent would not have allowed the '223 patent's claims if Kiani and Jensen did not withhold the documentation describing any of the Nellcor NPB-195, N-395, and OxiMax N-595 products from the USPTO.

During prosecution, Masimo, including named inventor Kiani and its prosecution attorney of record and client liaison Jensen, as well as other Masimo agents substantively involved in the prosecution of the '223 patent, knowingly withheld material documentation describing the Nellcor NPB-195, N-395, and OxiMax N-595 products from the USPTO. These were not merely peripheral references of which Kiani and Jensen merely had incidental awareness. Instead, at the same time that Kiani and Jensen withheld documentation describing the Nellcor NPB-195, OxiMax N-395, and N-595 products, Kiani and Jensen actively knew from multiple sources about material documentation describing the Nellcor NPB-195, N-395, and OxiMax N-595 products.

For example, in the time directly leading up to the prosecution of the '223 patent, Masimo and Nellcor were adverse parties in numerous litigations regarding Nellcor's pulse oximeter products. On October 8, 1999, Masimo sued Mallinckrodt Inc. and Nellcor Puritan Bennett, Inc. for patent infringement in the United States District Court for the Central District of California in Civil Action No. 8:99-cv-01245-AHS-AJW. In that litigation, Masimo was represented by Stephen Jensen, among other attorneys from Knobbe Martens. In that case, Masimo alleged that Nellcor's "N-395 stand-alone pulse oximeter" infringed Masimo's patent. *Masimo Corp. v. Mallinckrodt Inc.*, 18 F. App'x 852, 853–54 (Fed. Cir. 2001); *see also Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App'x 158, 164 (Fed. Cir. 2005) ("In 2000, Masimo sued Nellcor for infringement of claims 16 and 28 of U.S. Patent No. 6,036,642, asserting that Nellcor's N-395 and MP-404 pulse oximeters met all of the asserted claim limitations.").

Given Kiani's role as CEO of Masimo and Jensen's role as attorney of record in a litigation concerning the N-395 product, which went up on appeal to the Federal Circuit, on information and belief, at least Kiani and Jensen knew about documentation describing at least the Nellcor N-395 product.

Additionally, on November 17, 1999, Mallinckrodt Inc. and Nellcor Puritan Bennett, Inc. sued Masimo, and on December 8, 1999, Masimo counter-sued Mallinckrodt and Nellcor, for patent infringement in the United States District Court for the Central District of California in Civil Action No. 2:00-cv-06506-MRP-AJW. In that litigation, Masimo was represented by Stephen Jensen, among other attorneys from Knobbe Martens. Masimo's CEO Joe Kiani was directly involved in that litigation having signed multiple declarations on behalf of Masimo. *See, e.g., Mallinckrodt, Inc. v. Masimo Corp.*, No. 2:00-cv-06506-MRP-AJW, D.I. 265 (June 30, 2003 Declaration of Joe Kiani) & D.I. 389 (Jan. 20, 2004 Declaration of Joe Kiani). On August 4, 2004, the court entered Final Judgment where the court adjudged and decreed that Nellcor's manufacture, sale, offer to sell, use or importation of products including the N-395 and OxiMax N-595 monitors infringed several of Masimo's asserted patents. *See Mallinckrodt, Inc. v. Masimo Corp.*, No. 2:00-cv-06506-MRP-AJW, D.I. 632 (Aug. 4, 2004) (Final Judgment). Masimo then appealed aspects of the Court's decision in *Mallinckrodt, Inc. v. Masimo Corp.*, No. 2:00-cv-06506-MRP-AJW, after which the Federal Circuit ruled in Masimo's favor on multiple issues. *See Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App'x 158, 162 (Fed. Cir. 2005). In a press release regarding the Federal Circuit's decision, Masimo reported that "[t]he products found to infringe are Nellcor's O4 (Oxismart XL), O5 and O5ci (Oximax) technologies. ***Oxismart XL and Oximax technology are found in certain Nellcor pulse oximetry products, such as the N-595, N-395, N-550 and NPB40 pulse oximeters.***" (See <https://www.masimo.com/company/news/news-media/2005/#news->

1bcc85f5-3a5a-401d-8e4d-2a3c09fbade3, last accessed August 2, 2023) (emphasis added). That press release quoted Founder and CEO of Masimo Joe Kiani who provided comments about the case and, thus, knew about the Nellcor products accused in that case, including the N-395 and OxiMax N-595. Given Kiani and Jensen's involvement in that litigation, as well as the stage of that case proceeding through trial, on information and belief, Kiani and Jensen knew about the material documentation describing the Nellcor NPB-195, N-395, and OxiMax N-595 products.

Additionally, Nellcor Puritan Bennett, Inc. and Mallinckrodt Inc. became involved in another litigation with Masimo on December 10, 2002, when Nellcor and Mallinckrodt sued Masimo for patent infringement in United States District Court for the Central District of California in Civil Action No. 2:03-cv-00603-MR-AJ. That litigation ended—along with still pending claims that were remanded in the *Mallinckrodt, Inc. v. Masimo Corp.*, No. 2:00-cv-06506-MRP-AJW litigation following the Federal Circuit's ruling—on January 17, 2006, when Masimo and Nellcor entered into a settlement agreement that was signed by Joe Kiani on behalf of Masimo, further evidencing his awareness and knowledge of the Nellcor products and the material documents describing them. (See <https://www.sec.gov/Archives/edgar/data/937556/000119312507082880/dex1030.htm>, last accessed August 2, 2023).

At all relevant times, including during the prosecution of the '223 patent, Masimo, including Kiani and Jensen regarded Nellcor as Masimo's leading competitor in the pulse oximetry market. Indeed, on April 30, 2002, Kiani provided extensive testimony before the United States Senate regarding Nellcor. Among other things, Kiani testified that “our primary competitor, Tyco-Nellcor, [is] one of the largest companies in the world and already ha[s] 90% of the pulse oximetry market” and was “Masimo's leading and large[st] competitor.”

(https://www.judiciary.senate.gov/imo/media/doc/kiani_testimony_04_30_02.pdf, last accessed August 2, 2023). Thus, on information and belief, Masimo, including Kiani and Jensen, were well aware of the Nellcor pulse oximetry products and at least their publicly available substantive supporting documentation, such as the Operator's Manuals, including, for example, the Operator's Manuals for the NPB-195, N-395, and OxiMax N-595.

Unsurprisingly, Masimo, including named inventor Kiani, actively monitored the competing pulse oximeter product offerings of its primary and leading competitor Nellcor. Indeed, during his April 30, 2002 testimony before the United States Senate, Kiani repeatedly testified about Nellcor and its products, including Nellcor's N-395 product, which evidences his awareness of the Nellcor N-395 product and the Nellcor broader family of pulse oximetry products, including the closely related NPB-195 and OxiMax N-595. (*See* https://www.judiciary.senate.gov/imo/media/doc/kiani_testimony_04_30_02.pdf, last accessed August 2, 2023 (Kiani testifying regarding clear similarities between a Masimo pulse oximeter and Nellcor N-395, stating "[Nellcor] also told us that they would not let Masimo start the 'breakthrough technology' process until Tyco-Nellcor introduced its N-395, which Tyco-Nellcor had assured Premier would be equivalent to Masimo SET")). Moreover, Masimo and Kiani recognized and followed product comparisons between the Masimo pulse oximeters and the Nellcor N-395 and N-595. (*See* <https://www.masimo.com/company/news/news-media/2002/#news-234b74e6-4b58-4964-96c1-b39eafcb4ee6>, last accessed August 2, 2023 (10/18/2002 article on which Kiani commented that provides a product comparison between the "clinical performance of Masimo SET pulse oximetry compared to the Tyco-Nellcor N-395 and N-595")). Further, Masimo testified that Kiani conducted detailed tests of another competitor's product, thereby corroborating the fact that Kiani must have also tested and been well-aware of

the competing products of Masimo's primary competitor, Nellcor. *See Masimo Corp. v. Philips Elec. N. Am. Corp.*, No. CV 09-80-LPS, 2015 WL 2379485, at *20 (D. Del. May 18, 2015) ("Masimo presented evidence that its engineering team and Mr. Kiani tested PureSAT and confirmed it does not measure through motion (Tr. at 522–25, 635–36)."). Thus, on information and belief, Masimo and Kiani were themselves also studying and comparing the Nellcor pulse oximetry products, including the NPB-195, and N-395, and OxiMax N-595 products and their supporting documentation such as Operator's Manuals, when developing their own pulse oximetry products, and were well-aware of the materiality of each of these products and documents.

As discussed herein, on information and belief, Kiani, Jensen, and others at Masimo knew about Nellcor's pulse oximeters, including the Nellcor NPB-195, N-395, and OxiMax N-595 products, and the documentation describing those products, and knew of their materiality, yet specifically intended to, and did, withhold those material references from the USPTO during prosecution of the '223 patent. On information and belief, Kiani, Jensen, and other Masimo agents substantively involved in the prosecution of the '223 patent specifically intended to, and did, allow the examiners of the '223 patent to issue claims they would not have if Kiani, Jensen, and others at Masimo had disclosed any of the documentation describing the Nellcor NPB-195, N-395, or OxiMax N-595 products. Masimo is now asserting at least one of these claims against Apple.

None of the information disclosure statements submitted to the USPTO during prosecution of the '223 patent from March 2006 to April 2013 disclosed material technical features of the Nellcor NPB-195, N-395, or OxiMax N-595 products or Nellcor's material technical documentation describing the Nellcor NPB-195, N-395, or OxiMax N-595.

Named inventor Kiani and attorneys of record for the prosecution of the '223 patent including Jensen, however, had extensive knowledge of Nellcor and the withheld documentation

describing the Nellcor NPB-195, N-395, and OxiMax N-595 products during the prosecution of the '223 patent. Kiani founded Masimo in 1989. At all relevant times, including during the prosecution of the '223 patent, Kiani was the Chief Executive Officer and Chairman of the Board of Masimo. And as discussed above, Jensen was an attorney of record for Masimo in patent infringement litigation against Nellcor that concerned Nellcor products including the N-395 and OxiMax N-595.

On information and belief, Kiani, Jensen, and others at Masimo thus had deep knowledge of the materiality of each of the NPB-195, N-395, and OxiMax N-595 products and each of the material supporting documents publicly released for these products, particularly the Operator's Manuals, and their applicability as material prior art references. Despite this knowledge, Kiani, Jensen, and others at Masimo concealed those material prior art products and documents from the USPTO during prosecution of the '223 patent. On information and belief, they did so because they knew that identifying this information to the USPTO would have resulted in the USPTO rejecting the claims and not issuing the '223 patent—i.e., they each specifically intended to deceive the USPTO into issuing the '223 patent. The single most reasonable inference from this conduct is that they intended to deceive the USPTO into improperly allowing the '223 patent.

Accordingly, the '223 patent is unenforceable due to inequitable conduct.

The effect of this misconduct by Kiani, Jensen, and others at Masimo is not limited to the '223 patent. All subsequent “child” or other related patents that are based on the same specification or relevant portions thereof are tainted by Masimo's inequitable conduct and, therefore, are also unenforceable under the doctrine of infectious unenforceability.

'507 Patent — Withholding of Material Prior Art

The '507 patent is unenforceable due to inequitable conduct occurring during its prosecution, including, among other misconduct, Harnik Shukla, Jarom Kesler, and Stephen Jensen's withholding from the USPTO of key prior art that each of those individuals knew was material to patentability. Harnik Shukla, Jarom Kesler, and Stephen Jensen had extensive knowledge of this prior art at the relevant time and had disclosed it in another patent prosecution that took place in parallel with the prosecution of the '507 patent. These actions constitute fraud through omission because they violated the duty of disclosure owed by each of those individuals to the USPTO. These actions were all done with a specific intent to deceive the USPTO, which would not have issued the '507 patent if it had been made properly aware of the withheld prior art.

As discussed below, Harnik Shukla, Jarom Kesler, and Stephen Jensen are among the individuals who owed a duty of disclosure to the USPTO during the prosecution of the '507 patent and committed inequitable conduct by breaching that duty of disclosure. Each of these individuals was an attorney of record for prosecuting the application that resulted in the '507 patent.

Furthermore, Masimo and Knobbe Martens have an extensive 30-year relationship with overlapping members. For example, Jensen not only is a partner at Knobbe Martens, the law firm that prosecuted these patents, but also has served as Masimo's General Counsel and Senior Vice President of Original Equipment Manufacture (OEM) Business and Business Development and Jensen promotes himself as serving on the Board of Directors of Masimo affiliate Cercacor Corporation. (See <https://www.knobbe.com/attorneys/steve-jensen>, last accessed August 2, 2023). As another example, Jensen has been reported saying "I've represented [Masimo] since 1993 when they were a small group of engineers out of a very small office. . . I've represented them since almost the beginning." (See <https://www.ocbj.com/manufacturing/knobbe-partners-prep-for->

masimo-case/, last accessed August 2, 2023). Furthermore, Jensen and Knobbe Martens have been prosecuting Kiani and Masimo's patent applications since 1993 such that Masimo has "changed [Jensen's] personal and professional life immensely." (*See* <https://www.investors.com/news/management/leaders-and-success/masimo-ceo-four-guiding-principles-turn-startup-success/>, last accessed August 2, 2023). On information and belief, Kiani and others at Masimo selected the law firm Knobbe Martens to prosecute the '507 patent, the '745 patent, and other Masimo patents to exploit the 30-year commingled relationship that Masimo had with Knobbe Martens, which ensured total control over the prosecution process, including which material prior art to intentionally withhold from the USPTO to improperly obtain patents including the '507 patent.

Harnik Shukla

Harnik Shukla had a duty to disclose information material to the patentability of the '507 patent to the USPTO during prosecution of the '507 patent. Mr. Shukla is a partner at the law firm of Knobbe Martens and an attorney of record for prosecution of the '507 patent who prepared and prosecuted the application that resulted in the '507 patent.

For example, Mr. Shukla prepared, signed, and filed Masimo's September 30, 2019 Information Disclosure Statement that failed to disclose known material prior art during the prosecution of the '507 patent:

Docket No.: MAS.925C1

Customer No. 64735

INFORMATION DISCLOSURE STATEMENT

First Inventor	: Bilal Muhsin
App. No.	: 15/880071
Filed	: January 25, 2018
For	: PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY
Examiner	: Fardanesh, Marjan
Art Unit	: 3791
Conf. No.	: 4417

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a First Office Action, but before the mailing date of a Final Action and before the mailing date of a Notice of Allowance.

This Statement is accompanied by the fees set forth in 37 CFR 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Application No.: 15/880071

Filing Date: January 25, 2018

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 30, 2019

By: Harnik Shukla/

Harnik Shukla
Registration No. 73,097
Registered Practitioner
Customer No. 64735
(949) 721-5278

31422815

(’507 Prosecution, September 30, 2019 Information Disclosure Statement transmitted September 30, 2019).

In addition, the USPTO expressly lists Mr. Shukla as an attorney of record for prosecution of the ’507 patent.

Jarom Kesler

Jarom Kesler had a duty to disclose information material to the patentability of the ’507 patent to the USPTO during prosecution of the ’507 patent. Mr. Kesler is a partner at the law firm of Knobbe Martens and an attorney of record for prosecution of the ’507 patent who was substantively involved in the preparation and prosecution of the application that resulted in the ’507 patent.

For example, the USPTO expressly lists Mr. Kesler as an attorney of record for prosecution of the ’507 patent.

Stephen Jensen

Stephen Jensen had a duty to disclose information material to the patentability of the ’507 patent to the USPTO during prosecution of the ’507 patent. As a partner at the law firm of Knobbe Martens, Mr. Jensen was Masimo’s primary outside counsel and an attorney of record for prosecution of the ’507 patent who was substantively involved in the preparation and prosecution of the application that resulted in the ’507 patent.

For example, the USPTO expressly lists Mr. Jensen as an attorney of record for prosecution of the ’507 patent.

In addition to his own role as an attorney of record for prosecuting the ’507 patent, Mr. Jensen—as Masimo’s primary outside patent attorney and client liaison—was the Knobbe Martens partner who had ultimate responsibility for and control over Knobbe Martens’ legal work for

Masimo, including prosecution of the '507 patent. As such, Mr. Jensen had the incentive to, and as discussed below, did in fact prioritize his longstanding loyalties to Masimo over his duties of disclosure to the PTO to facilitate issuance of the '507 patent by committing inequitable conduct.

Mr. Kiani and others at Masimo selected the law firm of Knobbe Martens to prosecute the '507 patent to ensure that the firm with which Masimo had a 30-year commingled relationship would control the prosecution process, including which material prior art to withhold from the USPTO.

During prosecution of the '507 patent, Masimo, including through its prosecution attorneys of record Shukla, Kesler, and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '507 patent, withheld from the USPTO known prior art material to the patentability of the '507 patent—including Mendelson et al., “A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring,” Proceedings of the 28th IEEE EMBS Annual International Conference, August 30-September 3, 2006 (“Mendelson IEEE”)—with specific intent to deceive the USPTO.

Mendelson IEEE is prior art to the '507 patent and anticipates under 35 U.S.C. § 102 and/or renders obvious under 35 U.S.C. § 103, standing alone or combined with a person of ordinary skill in the art, at least claims 13, 14, 17, and 19 of the '507 patent. As shown in the attached exemplary claim chart, Mendelson IEEE discloses every element of at least claims 13, 14, 17, and 19 of the '507 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the '507 patent.

For example, the '507 patent claims “[a] computer-implemented method of informing a user of mobile measurement of oxygen saturation” utilizing an “optical sensor,” a “processing board,” and “an application.” '507 patent at claim 13.

Mendelson IEEE similarly discloses “a wireless wearable pulse oximeter developed based on a small forehead mounted sensor” that includes a processor and “wireless communication capabilities to transfer arterial oxygen saturation (SpO₂), heart rate (HR), body acceleration, and posture information to a PDA” and “[a] dedicated National Instruments LabVIEW program [which] was developed to control all interactions between the PDA and the wearable unit via a graphical user interface (GUI).” Mendelson IEEE at 1-3.

The '507 patent also claims “generating a graphical user interface having a plurality of display portions” and “displaying, in at least one portion of the plurality of display portions, a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO₂ measurement values” and “displaying, in a different portion of the plurality of portions, a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application.” '507 patent at claim 13.

Mendelson IEEE similarly discloses that “[t]he stream of data received from the wearable unit is distributed to various locations on the PDA’s graphical display. The most prominent portion of the GUI display is the scrolling PPG waveform, shown in Fig. 3. Numerical SpO₂ and HR values are displayed in separate indicator windows” and similarly that “[t]he user interacts with the wearable system using a simple GUI . . . [which] allows easy activation of various functions.” Mendelson IEEE at 3.

As such, the examiners for the '507 patent would not have allowed the '507 patent’s claims if Shukla, Kesler, and Jensen did not withhold Mendelson IEEE from the USPTO.

During prosecution, Masimo, including through its prosecution attorneys of record Shukla, Kesler, Jensen, as well as other Masimo agents substantively involved in the prosecution of the '507 patent, knowingly withheld Mendelson IEEE from the USPTO. This was not merely a

peripheral reference for which those individuals merely had incidental awareness. Instead, at the same time that Shukla, Kesler, and Jensen withheld Mendelson IEEE, those individuals knew about and indeed affirmatively cited Mendelson IEEE in the parallel prosecution of U.S. Patent No. 10,687,745 (“the ’745 patent”). As discussed further below, Shukla, Kesler, and Jensen and as well as other Masimo agents substantively involved in the prosecution of the ’507 patent, also prepared, prosecuted, and otherwise were substantively involved in preparing and prosecuting the ’745 patent, which was prosecuted on an expedited basis from filing to issuance all while the prosecution of the ’507 patent was ongoing. Indeed, Shukla, Kesler, and Jensen were responsible for prosecuting both the ’507 patent and the ’745 patent. Shukla, Kesler, Jensen and others at Masimo thus knew about Mendelson IEEE and its materiality yet specifically intended to, and did, withhold this material reference from the USPTO examiners of the ’507 patent. Shukla, Kesler, Jensen, and others at Masimo specifically intended to, and did, allow the examiners of the ’507 patent to issue claims they would not have if these individuals and others at Masimo had disclosed Mendelson IEEE to them. Masimo is now asserting at least one of these claims against Apple.

From January 2018 to August 2020, Masimo submitted two information disclosure statements to the USPTO when prosecuting the ’507 patent that identified only 12 references. Those information disclosure statements did not disclose or even mention Mendelson IEEE.

On April 23, 2020, however, Masimo cited Mendelson IEEE in an Information Disclosure Statement in its parallel prosecution of the ’745 patent. Shukla, Kesler, and Jensen thus were aware of Mendelson IEEE during the time that they were prosecuting the ’507 patent.

Shukla was aware of Mendelson IEEE during the prosecution of the ’507 patent. Shukla was an attorney of record for prosecution of the ’745 patent who was substantively involved in the preparation and prosecution of the application resulting in the ’745 patent.

Kesler was aware of Mendelson IEEE during the prosecution of the '507 patent. Kesler was an attorney of record for prosecution of the '745 patent who prepared and prosecuted the application resulting in the '745 patent.

Among other things, Kesler signed and filed documents submitted by Masimo during the prosecution of the '745 patent, including the April 23, 2020 Information Disclosure Statement that affirmatively cited Mendelson IEEE:

**INFORMATION DISCLOSURE STATEMENT
AND NOTICE OF CONCURRENT LITIGATION**

Inventor	: Ammar Al-Ali
App. No.	: 16/835,772
Filed	: March 31, 2020
For	: PHYSIOLOGICAL MONITORING DEVICES, SYSTEMS, AND METHODS
Examiner	: FARDANESH, MARJAN
Art Unit	: 3791
Conf. No.	: 2365

* * *

Timing of Disclosure

This Information Disclosure Statement is being filed before the receipt of a First Office Action on the merits, and presumably no fee is required. If a First Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 CFR 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 23, 2020

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Registered Practitioner
(949) 760-0404

* * *

	1303	Mendelson et al., "A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring," Proceedings of the 28th IEEE EMBS Annual International Conference, August 30-September 3, 2006, pp. 912-915.
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(’745 Prosecution, April 23, 2020 Information Disclosure Statement).

Jensen was aware of Mendelson IEEE during the prosecution of the ’507 patent. From January 2018 to August 2020, Jensen also was an attorney of record for prosecution of the ’745 patent who was substantively involved in the preparation and prosecution of the application that resulted in the ’745 patent.

As Masimo’s primary outside patent attorney and client liaison, Mr. Jensen also had ultimate responsibility for and control over this prosecution.

At least Shukla, Kesler, and Jensen thus had deep knowledge of Mendelson IEEE and its applicability as a prior art reference. Despite this knowledge, Shukla, Kesler, Jensen, and others at Masimo concealed Mendelson IEEE from the USPTO during prosecution of the ’507 patent. On information and belief, they did so because they knew that identifying this information to the USPTO would have resulted in the USPTO rejecting the claims and not issuing the ’507 patent—i.e., they each specifically intended to deceive the USPTO into issuing the ’507 patent. The single most reasonable inference from this conduct is that they intended to deceive the USPTO into improperly allowing the ’507 patent.

Accordingly, the ’507 patent is unenforceable due to inequitable conduct.

The effect of Shukla, Kesler, and Jensen’s conduct is not limited to the ’507 patent. All subsequent “child” or other related patents that are based on the same specification or relevant portions thereof are tainted by Masimo’s inequitable conduct and, therefore, are also unenforceable under the doctrine of infectious unenforceability.

'743 Patent — Burying of Material Prior Art

The '743 patent is unenforceable due to inequitable conduct occurring during its prosecution, including, among other misconduct, Jarom Kesler and Stephen Jensen burying key prior art references that each of those individuals knew were material to patentability. Specifically, during prosecution of the '743 patent, Jarom Kesler and Stephen Jensen intentionally buried known, highly material prior art among voluminous submissions of less relevant and even clearly irrelevant prior art. Jarom Kesler and Stephen Jensen's pattern of misconduct evidenced specific intent to deceive the USPTO, which would not have issued the '743 patent if it had been made properly aware of the buried references.

As discussed below, Jarom Kesler and Stephen Jensen are among the individuals who owed a duty of disclosure to the USPTO during the prosecution of the '743 patent and committed inequitable conduct by breaching that duty of disclosure. Each of these individuals was an attorney of record for prosecuting the application that resulted in the '743 patent.

Jarom Kesler

Jarom Kesler had a duty to disclose information material to the patentability of the '743 patent to the USPTO during prosecution of the '743 patent. Mr. Kesler is a partner at the law firm of Knobbe Martens and an attorney of record for prosecution of the '743 who prepared and prosecuted the application resulting in the '743 patent. Among other things, Mr. Kesler signed and filed documents submitted by Masimo during prosecution of the '743 patent, including Masimo's February 14, 2020 Patent Application; February 14, 2020 Request for Prioritized Examination; March 11, 2020 Rescission of any Prior Disclaimers and Request to Revisit Art, March 11, 2020 Amendments, March 11, 2020 Information Disclosure Statement; March 30, 2020 Interview; April 8, 2020 Information Disclosure Statement and Notice of Concurrent Litigation;

April 15, 2020 Comments on Statement of Reasons for Allowance; and August 10, 2020 Certificate of Correction.

Among other things, Mr. Kesler prepared, signed, and filed Masimo's March 11, 2020 Information Disclosure Statement, which cited no fewer than **1,339** prior art references. This March 11, 2020 Information Disclosure Statement included all of the same 1,339 references that were included in the Information Disclosure Statement submitted for a different patent, the '159 patent, on the same date.

INFORMATION DISCLOSURE STATEMENT

First Inventor	:	Ammar Al-Ali
App. No.	:	16/791955
Filed	:	February 14, 2020
For	:	PHYSIOLOGICAL MEASUREMENT DEVICES, SYSTEMS, AND METHODS
Examiner	:	Unassigned
Art Unit	:	2875
Conf. No.	:	3106

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. References numbered 1-1219 and 1221-1339 are of record in U.S. patent application No. 16/532061, filed August 5, 2019, which is relied upon for an earlier filing date under 35 USC 120. Accordingly, copies of references 1-1219 and 1221-1339 are not submitted pursuant to 37 CFR 1.98(d).

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed within three months of the filing date or date of national phase entry, with an RCE or before receipt of a First Office Action after an RCE, and no fee is believed to be required.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 11, 2020

By: /Jarom Kesler/

Jarom D. Kesler
Registration No. 57,046
Registered Practitioner
Customer No. 64735
(949) 760-0404

(‘743 Prosecution, March 11, 2020 Information Disclosure Statement).

Among other things, Mr. Kesler also prepared, signed, and filed Masimo’s February 14, 2020 Request for Prioritized Examination, which was granted on March 5, 2020.

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)			
First Named Inventor:	Ammar Al-Ali	Nonprovisional Application Number (if known):	Unassigned
Title of Invention:	PHYSIOLOGICAL MEASUREMENT DEVICES, SYSTEMS, AND METHODS		
<p>APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.</p> <ol style="list-style-type: none"> 1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application. 2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed. 3. The applicable box is checked below: <ol style="list-style-type: none"> I. <input checked="" type="checkbox"/> Original Application (Track One) - Prioritized Examination under § 1.102(e)(1) <ol style="list-style-type: none"> i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web. ---OR--- (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper. ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application. II. <input type="checkbox"/> Request for Continued Examination - Prioritized Examination under § 1.102(e)(2) <ol style="list-style-type: none"> i. A request for continued examination has been filed with, or prior to, this form. ii. If the application is a utility application, this certification and request is being filed via EFS-Web. iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371. iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination. v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2). 			
Signature <u>/Jarom Kesler/</u>		Date <u>2020-02-14</u>	
Name (Print/Typed) <u>Jarom D. Kesler</u>		Practitioner Registration Number <u>57046</u>	
<p>Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*</p>			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

(‘743 Prosecution, February 14, 2020 Certification and Request for Prioritized Examination).

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 16/791,955	Applicant(s) Al-Ali, Ammar	
	Examiner BRIAN W BROWN	Art Unit OPET	AIA (FITF) Status Yes
<p>1. THE REQUEST FILED <u>14 February 2020</u> IS GRANTED.</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I).</p> <p>B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a petition for extension of time to extend the time period for filing a reply;</p> <p>B. filing an amendment to amend the application to contain more than four independent claims, more than thirty total claims, or a multiple dependent claim;</p> <p>C. filing a request for continued examination ;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to BRIAN BROWN at (571)272-5338. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.</p>			
/BRIAN W BROWN/ Petitions Examiner, OPET			

('743 Prosecution, March 5, 2020 Decision Granting Request for Prioritized Examination).

Stephen Jensen

Stephen Jensen had a duty to disclose information material to the patentability of the '743 patent to the USPTO during prosecution of the '743 patent. As a partner at the law firm of Knobbe Martens, Mr. Jensen was Masimo's primary outside counsel and an attorney of record for

prosecution of the '743 patent who was substantively involved in the preparation and prosecution of the application that resulted in the '743 patent.

For example, the USPTO expressly lists Mr. Jensen as an attorney of record for prosecution of the '743 patent.

In addition to his own role as an attorney of record for prosecuting the '743 patent, Mr. Jensen—as Masimo's primary outside patent attorney and client liaison—was the Knobbe Martens partner who had ultimate responsibility for and control over Knobbe Martens' legal work for Masimo, including prosecution of the '743 patent. As such, Mr. Jensen had the incentive to, and as discussed below, did in fact prioritize his longstanding loyalties to Masimo over his duties of disclosure to the PTO to facilitate issuance of the '743 patent by committing inequitable conduct.

Mr. Kiani and others at Masimo selected the law firm of Knobbe Martens to prosecute the '743 patent to ensure that the firm with which Masimo had a 30-year commingled relationship would control the prosecution process, including which material prior art to withhold from the USPTO or otherwise bury under voluminous disclosures of irrelevant prior art, as discussed further below.

During prosecution of the '743 patent, Masimo, through its prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, submitted unreasonably voluminous prior art disclosures to obscure five of the most important prior art references, namely U.S. Pub. No. US2011/0004106 to Iwamiya et al. ("Iwamiya"), U.S. Patent No. 6,801,799 to Mendelson ("Mendelson 799"), U.S. Patent No. 6,343,223 to Chin et al. ("Chin"), U.S. Patent No. 5,099,842 to Mannheimer et al. ("Mannheimer 842"), and U.S. Patent No. 6,580,086 to Schulz et al. ("Schulz"). Masimo's prosecution attorneys cited no fewer than 1,339 references in an Information Disclosure Statement submitted during

prosecution. Masimo's March 11, 2020 Information Disclosure Statement, which essentially comprised a document dump of these 1,339 references, included numerous clearly irrelevant and (at best) marginally relevant references. Because these references were buried amongst 1,339 disclosed references, the patent examiner could not have considered each of them and, in fact, did not cite them in any office action.

Among the 1,339 cited references was Iwamiya. Iwamiya concerns an optical biological information detecting apparatus and teaches "a light emitting unit which emits observation light of a specific wavelength band to optically observe a desired portion of a tissue; an annular light guide unit which guides the observation light to a desired area of a surface of the skin...; and a light receiving unit which is disposed at a position surrounded by the annular light guide unit..." Iwamiya at claim 1. Iwamiya is prior art to the '743 patent, and at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the '743 patent are invalid as anticipated by Iwamiya under 35 U.S.C. § 102 or as obvious under § 103 in view of Iwamiya standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Iwamiya (charted as U.S. Patent No. 8,670,819) discloses every element of at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the '743 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the '743 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, knew during the prosecution of the '743 patent that Iwamiya existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '743 patent, as evidenced by the submission of Masimo's March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Iwamiya was material to patentability of the '743 patent.

Also among the 1,339 cited references was Chin. Chin concerns oximeter sensors with a heating element to improve blood perfusion, and the patent teaches “[a]n oximeter sensor comprising . . . a light emitter mounted on a first side of a tissue region of a patient . . . [and] a light detector mounted on a second side of said tissue region of said patient[.]” Chin at 10:25-30. Chin is prior art to the ’743 patent, and at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the ’743 patent are invalid as anticipated by Chin under 35 U.S.C. § 102 or as obvious under § 103 in view of Chin standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Chin discloses every element of at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the ’743 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the ’743 patent.

Masimo’s prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’743 patent, knew during the prosecution of the ’743 patent that Chin existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the ’743 patent, as evidenced by the submission of Masimo’s March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Chin was material to patentability of the ’743 patent.

Among the 1,339 cited references was Mendelson 799. Mendelson 799 concerns non-invasive blood parameter measurements and teaches “[a] sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter.” Mendelson 799 at Abstract. Mendelson 799 is prior art to the ’743 patent, and at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the ’743 patent are invalid as obvious under § 103 in view of Mendelson 799 standing alone, or combined with a person of ordinary skill in the art. As shown in the attached

exemplary claim chart, Mendelson 799 contains disclosures material to the invalidity of the asserted claims of the '743 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, knew during the prosecution of the '743 patent that Mendelson 799 existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '743 patent, as evidenced by the submission of Masimo's March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Mendelson 799 was material to patentability of the '743 patent.

Also among the 1,339 cited references was Mannheimer 842. Mannheimer 842 concerns a fetal pulse oximetry probe and teaches "[a] transreflectance-type pulse oximetry probe comprising . . . a light source and a light detector mounted within a probe" Mannheimer 842 at 4:35-38. Mannheimer 842 is prior art to the '743 patent, and at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the '743 patent are invalid as obvious under § 103 in view of Mannheimer 842 standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Mannheimer 842 contains disclosures material to the invalidity of the asserted claims of the '743 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, knew during the prosecution of the '743 patent that Mannheimer 842 existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '743 patent, as evidenced by the submission of Masimo's March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Mannheimer 842 was material to patentability of the '743 patent.

Also among the 1,339 cited references was Schulz. Schulz concerns an optical probe for use in measurements on tissue material of a patient, including for blood oximetry. Schulz teaches an “optical probe for use in non-invasive energy absorption or reflection measurements, as well as a method of using the same.” Schulz at 3:46-48. Schulz is prior art to the ’743 patent, and at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 of the ’743 patent are invalid as obvious under § 103 in view of Schulz standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Schulz contains disclosures material to the invalidity of the asserted claims of the ’743 patent.

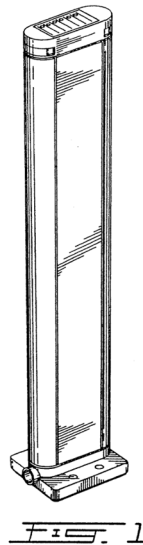
Masimo’s prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’743 patent, knew during the prosecution of the ’743 patent that Schulz existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the ’743 patent, as evidenced by the submission of Masimo’s March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Schulz was material to patentability of the ’743 patent.

Accordingly, the buried Iwamiya reference, Mendelson 799 reference, Chin reference, Mannheimer 842 reference, and Schulz reference were, at the very least, highly material to patentability of the alleged inventions claimed in what would become the ’743 patent.

Masimo, through its prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’743 patent, submitted two Information Disclosure Statements during prosecution of the patent application that led to the ’743 patent on the following dates: March 11, 2020 and April 8, 2020. These Information Disclosure Statements listed 1,339 prior art references, a substantial number of which were clearly irrelevant

or at most minimally relevant to the alleged inventions covered by the pending claims at any point during prosecution.

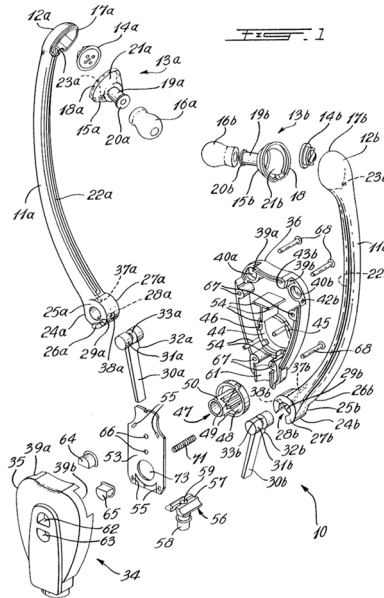
One example of an irrelevant (or at most minimally relevant) reference submitted to the USPTO is U.S. Patent No. Des. 359,546 to Savage et al. (“Savage”), titled “Housing for a dental unit disinfecting device.” Whereas the ’743 patent concerns a non-invasive, optical-based physiological monitoring sensor, Savage, a design-patent reference, concerns very different subject matter—the ornamental design for a housing for a dental unit disinfecting device. Shown in Figure 1 below is a perspective view of the housing for a dental unit disinfecting device.



This subject matter is far afield from that of the ’743 patent and had the effect of obscuring and thereby burying the most material references, including at least Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz.

Another example of an irrelevant (or at most minimally relevant) reference submitted to the USPTO is U.S. Patent No. 6,595,316 to Cybulski et al. (“Cybulski”), titled “Tension-adjustable mechanism for stethoscope earpieces.” Whereas the ’743 patent concerns a non-invasive, optical-

based physiological monitoring sensor, this reference concerns very different subject matter—stethoscope earpieces. For example, the patent discloses a “tension-adjustable headset for [an] electronic stethoscope.” Cybulski at 3:42-43. Figure 1 below shows said headset.



This subject matter is far afield from that of the '743 patent and had the effect of obscuring and thereby burying the most pertinent references, including Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz.

During prosecution of the '743 patent, Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent submitted the March 11, 2020 and April 8, 2020 Information Disclosure Statements, burying the USPTO with at least 1,339 references. Buried in these unreasonably voluminous submissions were the material Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz. Out of the 1,339 references cited in the March 11, 2020 Information Disclosure Statement, the Iwamiya reference was document 769, the Mendelson 799 reference was document 158, the Chin reference

was document 101, the Mannheimer 842 reference was document 5, and the Schulz reference was document 123.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, were aware of the relevance and high materiality of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz. They knew that Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz existed because they included them in Information Disclosure Statements, and by submitting them in Information Disclosure Statements, thereby acknowledged their relevance to the prosecution of the application leading to the '743 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, therefore had knowledge of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz as well as their materiality to patentability, at least giving rise to an inference of intentional breach of their duties of disclosure.

Although Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz were submitted into the file history in the patent application that matured into the '743 patent via citations in the Information Disclosure Statement, these references were buried within a large number of other less relevant or irrelevant documents and were never brought to the examiner's attention.

Notably, despite their knowledge of the contents and materiality of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz, Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, failed to highlight these references or otherwise distinguish them in any way from the other 1,000-plus cited references at any point during the prosecution of what would become the '743

patent. And Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz are not cumulative of other prior art relied on by the examiner.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '743 patent, thus buried Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz and failed to bring those references to the examiner's attention to intentionally mislead the examiner in order to improperly procure the '743 patent, notwithstanding that Masimo was not entitled to such patent based on Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz under 35 U.S.C. §§ 102, 103.

Masimo's prosecution attorneys of record Kesler and Jensen sought expedited review, which was granted on March 5, 2020. Only six days later, on March 11, 2020, Masimo's prosecution attorneys of record Kesler and Jensen submitted 1,339 prior art references for the patent examiner's review. Bound by USPTO's agreement to review the prosecution on an expedited basis, the patent examiner signed that March 11, 2020 Information Disclosure Statement on March 19, 2020, only eight days after receiving it, stating that the patent examiner has considered the 1,339 prior art references. It defies reality that the patent examiner could have actually obtained, read, and considered 1,339 prior art references in just eight days. On April 9, 2020, only a few weeks later, the patent examiner issued its Notice of Allowance. Accordingly, by requesting expedited review and then submitting 1,339 prior art references for review on a compressed schedule, Masimo's prosecution attorneys of record Kesler and Jensen compounded the USPTO's inability to review the 1,339 prior art references with appropriate scrutiny. Therefore, the patent examiner could not possibly have read each reference that Masimo's prosecution attorneys of record had identified. The single most reasonable inference that can be drawn from the evidence is that Masimo's prosecution attorneys of record intended to deceive the

USPTO by burying the patent examiner with prior art and leaving the patent examiner with no practical way to review everything that was disclosed or figure out what was pertinent among the 1,339 listed references.

But for this misleading conduct, the examiner would have cited either or all of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz alone or in combination with other cited references to reject the claims of the '743 patent, including at least claims 1, 4-8, 11-12, 14, 16, 18-19, and 21 as invalid.

Accordingly, the '743 patent is unenforceable due to inequitable conduct.

The effect of Kesler and Jensen's conduct is not limited to the '743 patent. All subsequent "child" or other related patents that are based on the same specification or relevant portions thereof are tainted by Masimo's inequitable conduct and, therefore, are also unenforceable under the doctrine of infectious unenforceability.

'159 Patent — Burying of Material Prior Art

The '159 patent is unenforceable due to inequitable conduct occurring during its prosecution, including, among other misconduct, Jarom Kesler and Stephen Jensen's burying key prior art references that each of those individuals knew were material to patentability. Specifically, during prosecution of the '159 patent, Jarom Kesler and Stephen Jensen intentionally buried known, highly material prior art among voluminous submissions of less relevant and even clearly irrelevant prior art. Jarom Kesler and Stephen Jensen's pattern of misconduct evidenced specific intent to deceive the USPTO, which would not have issued the '159 patent if it had been made properly aware of the buried references.

As discussed below, Jarom Kesler and Stephen Jensen are among the individuals who owed a duty of disclosure to the USPTO during the prosecution of the '159 patent and committed

inequitable conduct by breaching that duty of disclosure. Each of these individuals was an attorney of record for prosecuting the application that resulted in the '159 patent.

Jarom Kesler

Jarom Kesler had a duty to disclose information material to the patentability of the '159 patent to the USPTO during prosecution of the '159 patent. Mr. Kesler is a partner at the law firm of Knobbe Martens and an attorney of record for prosecution of the '159 who prepared and prosecuted the application resulting in the '159 patent. Among other things, Mr. Kesler signed and filed documents submitted by Masimo during prosecution of the '159 patent, including Masimo's February 14, 2020 Patent Application; February 24, 2020 Request for Prioritized Examination; March 11, 2020 Rescission of any Prior Disclaimers and Request to Revisit Art, March 11, 2020 Amendments, March 11, 2020 Information Disclosure Statement; April 8, 2020 Information Disclosure Statement and Notice of Concurrent Litigation; April 21, 2020 Comments on Statement of Reasons for Allowance; and August 10, 2020 Certificate of Correction.

Among other things, Mr. Kesler prepared, signed, and filed Masimo's March 11, 2020 Information Disclosure Statement, which cited no fewer than **1,339** prior art references. This March 11, 2020 Information Disclosure Statement included all of the same 1,339 references that were included in the Information Disclosure Statement submitted for a different patent, the '743 patent, on the same date.

INFORMATION DISCLOSURE STATEMENT

First Inventor	:	Ammar Al-Ali
App. No.	:	16/791963
Filed	:	February 14, 2020
For	:	PHYSIOLOGICAL MONITORING DEVICES, SYSTEMS, AND METHODS
Examiner	:	Unassigned
Art Unit	:	3791
Conf. No.	:	4439

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. References numbered 1-1219 and 1221-1339 are of record in U.S. patent application No. 16/532065, filed August 5, 2019, which is relied upon for an earlier filing date under 35 USC 120. Accordingly, copies of references 1-1219 and 1221-1339 are not submitted pursuant to 37 CFR 1.98(d).

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed within three months of the filing date or date of national phase entry, with an RCE or before receipt of a First Office Action after an RCE, and no fee is believed to be required.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 11, 2020

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Registered Practitioner
Customer No. 64735
(949) 760-0404

(‘159 Prosecution, March 11, 2020 Information Disclosure Statement).

Among other things, Mr. Kesler also prepared, signed, and filed Masimo’s February 24, 2020 Request for Prioritized Examination, which was granted on March 5, 2020.

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)			
First Named Inventor:	Ammar Al-Ali	Nonprovisional Application Number (if known):	Unassigned
Title of Invention:	PHYSIOLOGICAL MONITORING DEVICES, SYSTEMS, AND METHODS		
APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.			
<ol style="list-style-type: none"> 1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application. 2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed. 3. The applicable box is checked below: <div style="margin-left: 20px;"> <p>I. <input checked="" type="checkbox"/> Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)</p> <p>i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web. ---OR---</p> <p>(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.</p> <p>ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.</p> <p>II. <input type="checkbox"/> Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)</p> <p>i. A request for continued examination has been filed with, or prior to, this form.</p> <p>ii. If the application is a utility application, this certification and request is being filed via EFS-Web.</p> <p>iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.</p> <p>iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.</p> <p>v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).</p> </div> 			
Signature <u>/Jarom Kesler/</u>		Date <u>2020-02-24</u>	
Name (Print/Typed) <u>Jarom D. Kesler</u>		Practitioner Registration Number <u>57046</u>	
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

(159 Prosecution, February 24, 2020 Certification and Request for Prioritized Examination).

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 16/791,963	Applicant(s) Al-Ali, Ammar	
	Examiner CHERYL P GIBSON BAYLOR	Art Unit OPET	AIA (FITF) Status Yes
<p>1. THE REQUEST FILED <u>14 February 2020</u> IS GRANTED.</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I).</p> <p>B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a petition for extension of time to extend the time period for filing a reply;</p> <p>B. filing an amendment to amend the application to contain more than four independent claims, more than thirty total claims, or a multiple dependent claim;</p> <p>C. filing a request for continued examination ;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.</p>			
/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET			

('159 Prosecution, March 5, 2020 Decision Granting Request for Prioritized Examination).

Stephen Jensen

Stephen Jensen had a duty to disclose information material to the patentability of the '159 patent to the USPTO during prosecution of the '159 patent. As a partner at the law firm of Knobbe Martens, Mr. Jensen was Masimo's primary outside counsel and an attorney of record for

prosecution of the '159 patent who was substantively involved in the preparation and prosecution of the application that resulted in the '159 patent.

For example, the USPTO expressly lists Mr. Jensen as an attorney of record for prosecution of the '159 patent.

In addition to his own role as an attorney of record for prosecuting the '159 patent, Mr. Jensen—as Masimo's primary outside patent attorney and client liaison—was the Knobbe Martens partner who had ultimate responsibility for and control over Knobbe Martens' legal work for Masimo, including prosecution of the '159 patent. As such, Mr. Jensen had the incentive to, and as discussed below, did in fact prioritize his longstanding loyalties to Masimo over his duties of disclosure to the PTO to facilitate issuance of the '159 patent by committing inequitable conduct.

Mr. Kiani and others at Masimo selected the law firm of Knobbe Martens to prosecute the '159 patent to ensure that the firm with which Masimo had a 30-year commingled relationship would control the prosecution process, including which material prior art to withhold from the USPTO or otherwise bury under voluminous disclosures of irrelevant prior art, as discussed further below.

During prosecution of the '159 patent, Masimo, through its prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, submitted unreasonably voluminous prior art disclosures to obscure five of the most important prior art references, namely U.S. Pub. No. US2011/0004106 to Iwamiya et al. ("Iwamiya"), U.S. Patent No. 6,801,799 to Mendelson ("Mendelson 799"), U.S. Patent No. 6,343,223 to Chin et al. ("Chin"), U.S. Patent No. 5,099,842 to Mannheimer et al. ("Mannheimer 842"), and U.S. Patent No. 6,580,086 to Schulz et al. ("Schulz"). Masimo's prosecution attorneys cited no fewer than 1,339 references in Information Disclosure Statements submitted during

prosecution. Masimo's March 11, 2020 Information Disclosure Statement, which essentially comprised a document dump of these 1,339 references, included numerous clearly irrelevant and (at best) marginally relevant references. Because these references were buried amongst 1,339 disclosed references, the patent examiner could not have considered each of them and, in fact, did not cite them in any office action.

Among the 1,339 cited references was Iwamiya. Iwamiya concerns an optical biological information detecting apparatus and teaches "a light emitting unit which emits observation light of a specific wavelength band to optically observe a desired portion of a tissue; an annular light guide unit which guides the observation light to a desired area of a surface of the skin . . . ; and a light receiving unit which is disposed at a position surrounded by the annular light guide unit" Iwamiya at claim 1. Iwamiya is prior art to the '159 patent, and at least claims 1-5, 7-9, 13, 19-23, and 25 of the '159 patent are invalid as anticipated by Iwamiya under 35 U.S.C. § 102 or as obvious under § 103 in view of Iwamiya standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Iwamiya (charted as U.S. Patent No. 8,670,819) discloses every element of at least claims 1-5, 7-9, 13, 19-23, and 25 of the '159 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the '159 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, knew during the prosecution of the '159 patent that Iwamiya existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '159 patent, as evidenced by the submission of Masimo's March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Iwamiya was material to patentability of the '159 patent.

Also among the 1,339 cited references was Chin. Chin concerns oximeter sensors with a heating element to improve blood perfusion, and the patent teaches “[a]n oximeter sensor comprising . . . a light emitter mounted on a first side of a tissue region of a patient . . . [and] a light detector mounted on a second side of said tissue region of said patient[.]” Chin at 10:25-30. Chin is prior art to the ’159 patent, and at least claims 1-5, 7-9, 13, 19-23, and 25 of the ’159 patent are invalid as anticipated by Chin under 35 U.S.C. § 102 or as obvious under § 103 in view of Chin standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Chin discloses every element of at least claims 1-5, 7-9, 13, 19-23, and 25 of the ’159 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the ’159 patent.

Masimo’s prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’159 patent, knew during the prosecution of the ’159 patent that Chin existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the ’159 patent, as evidenced by the submission of Masimo’s March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Chin was material to patentability of the ’159 patent.

Among the 1,339 cited references was Mendelson 799. Mendelson 799 concerns non-invasive blood parameter measurements and teaches “[a] sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter.” Mendelson 799 at Abstract. Mendelson 799 is prior art to the ’159 patent, and at least claims 1-5, 7-9, 13, 19-23, and 25 of the ’159 patent are invalid as obvious under § 103 in view of Mendelson 799 standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim

chart, Mendelson 799 contains disclosures material to the invalidity of the asserted claims of the '159 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, knew during the prosecution of the '159 patent that Mendelson 799 existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '159 patent, as evidenced by the submission of Masimo's March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Mendelson 799 was material to patentability of the '159 patent.

Also among the 1,339 cited references was Mannheimer 842. Mannheimer 842 concerns a fetal pulse oximetry probe and teaches "[a] transreflectance-type pulse oximetry probe comprising . . . a light source and a light detector mounted within a probe" Mannheimer 842 at 4:35-38. Mannheimer 842 is prior art to the '159 patent, and at least claims 1-5, 7-9, 13, 19-23, and 25 of the '159 patent are invalid as obvious under § 103 in view of Mannheimer 842 standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Mannheimer 842 contains disclosures material to the invalidity of the asserted claims of the '159 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, knew during the prosecution of the '159 patent that Mannheimer 842 existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '159 patent, as evidenced by the submission of Masimo's March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Mannheimer 842 was material to patentability of the '159 patent.

Also among the 1,339 cited references was Schulz. Schulz concerns an optical probe for use in measurements on tissue material of a patient, including for blood oximetry. Schulz teaches an “optical probe for use in non-invasive energy absorption or reflection measurements, as well as a method of using the same.” Schulz at 3:46-48. Schulz is prior art to the ’159 patent, and at least claims 1-5, 7-9, 13, 19-23, and 25 of the ’159 patent are invalid as obvious under § 103 in view of Schulz standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Schulz contains disclosures material to the invalidity of the asserted claims of the ’159 patent.

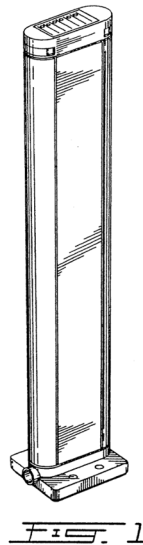
Masimo’s prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’159 patent, knew during the prosecution of the ’159 patent that Schulz existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the ’159 patent, as evidenced by the submission of Masimo’s March 11, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Schulz was material to patentability of the ’159 patent.

Accordingly, the buried Iwamiya, Mendelson 799 reference, Chin reference, Mannheimer 842 reference, and Schulz reference were, at the very least, highly material to patentability of the alleged inventions claimed in what would become the ’159 patent.

Masimo, through its prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’159 patent, submitted two Information Disclosure Statements during prosecution of the patent application that led to the ’159 patent on the following dates: March 11, 2020 and April 8, 2020. These Information Disclosure Statements listed 1,339 prior art references, a substantial number of which were clearly irrelevant

or at most minimally relevant to the alleged inventions covered by the pending claims at any point during prosecution.

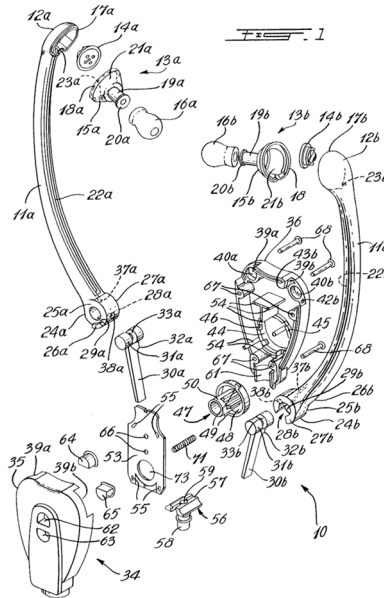
One example of an irrelevant (or at most minimally relevant) reference submitted to the USPTO is U.S. Patent No. Des. 359,546 to Savage et al. (“Savage”), titled “Housing for a dental unit disinfecting device.” Whereas the ’159 patent concerns a non-invasive, optical-based physiological monitoring sensor, Savage, a design-patent reference, concerns very different subject matter—the ornamental design for a housing for a dental unit disinfecting device. Shown in Figure 1 below is a perspective view of the housing for a dental unit disinfecting device.



This subject matter is far afield from that of the ’159 patent and had the effect of obscuring and thereby burying the most material references, including at least Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz.

Another example of an irrelevant or at most minimally relevant reference submitted to the USPTO is U.S. Patent No. 6,595,316 to Cybulski et al. (“Cybulski”), titled “Tension-adjustable mechanism for stethoscope earpieces.” Whereas the ’159 patent concerns a non-invasive, optical-

based physiological monitoring sensor, this reference concerns very different subject matter—stethoscope earpieces. For example, the patent discloses a “tension-adjustable headset for [an] electronic stethoscope.” Cybulski at 3:42-43. Figure 1 below shows said headset.



This subject matter is far afield from that of the '159 patent and had the effect of obscuring and thereby burying the most pertinent references, including Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz.

During prosecution of the '159 patent, Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent submitted the March 11, 2020 and April 8, 2020 Information Disclosure Statements above, burying the USPTO with at least 1,339 references. Buried in these unreasonably voluminous submissions were the material Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz. Out of the 1,339 references cited in the March 11, 2020 Information Disclosure Statement, the Iwamiya reference was document 769, the Mendelson 799 reference was document 157, the Chin reference

was document 100, the Mannheimer 842 reference was document 5, and the Schulz reference was document 122.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, were aware of the relevance and high materiality of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz. They knew that Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz existed because they included them in an Information Disclosure Statement, and by submitting them in an Information Disclosure Statement, thereby acknowledged their relevance to the prosecution of the application leading to the '159 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, therefore had knowledge of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz as well as their materiality to patentability, at least giving rise to an inference of intentional breach of their duties of disclosure.

Although Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz were submitted into the file history in the patent application that matured into the '159 patent via citations in an Information Disclosure Statement, these references were buried within a large number of other less relevant or irrelevant documents and were never brought to the examiner's attention.

Notably, despite their knowledge of the contents and materiality of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz, Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, failed to highlight these references or otherwise distinguish them in any way from the other 1,000-plus cited references at any point during the prosecution of what would become the '159

patent. And Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz are not cumulative of other prior art relied on by the examiner.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '159 patent, thus buried Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz and failed to bring those references to the examiner's attention to intentionally mislead the examiner in order to improperly procure the '159 patent, notwithstanding that Masimo was not entitled to such patent based on Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz under 35 U.S.C. §§ 102, 103.

Masimo's prosecution attorneys of record Kesler and Jensen sought expedited review, which was granted on March 5, 2020. Only six days later, on March 11, 2020, Masimo's prosecution attorneys of record Kesler and Jensen submitted 1,339 prior art references for the patent examiner's review. Bound by USPTO's agreement to review the prosecution on an expedited basis, the patent examiner signed that March 11, 2020 Information Disclosure Statement on March 19, 2020, only eight days after receiving it, stating that the patent examiner has considered the 1,339 prior art references. It defies reality that the patent examiner could have actually obtained, read, and considered 1,339 prior art references in just eight days. On April 9, 2020, only a few weeks later, the patent examiner issued its Notice of Allowance. Accordingly, by requesting expedited review and then submitting 1,339 prior art references for review on a compressed schedule, Masimo's prosecution attorneys of record Kesler and Jensen compounded the USPTO's inability to review the 1,339 prior art references with appropriate scrutiny. On information and belief, this conduct was specifically intended to, and did, obscure material references from the examiner among many minimally relevant references. Therefore, the patent examiner could not possibly have read each reference that Masimo's prosecution attorneys of

record had identified. The single most reasonable inference that can be drawn from the evidence is that Masimo's prosecution attorneys of record intended to deceive the USPTO by burying the patent examiner with prior art and leaving the patent examiner with no practical way to review everything that was disclosed or figure out what was pertinent among the 1,339 listed references.

But for this misleading conduct, the examiner would have cited either or all of Iwamiya, Mendelson 799, Chin, Mannheimer 842, and Schulz alone or in combination with other cited references to reject the claims of the '159 patent, including at least claims 1-5, 7-9, 13, 19-23, and 25, as invalid.

Accordingly, the '159 patent is unenforceable due to inequitable conduct.

The effect of Kesler and Jensen's conduct is not limited to the '159 patent. All subsequent "child" or other related patents that are based on the same specification or relevant portions thereof are tainted by Masimo's inequitable conduct and, therefore, are also unenforceable under the doctrine of infectious unenforceability.

'911 Patent — Burying of Material Prior Art

The '911 patent is unenforceable due to inequitable conduct occurring during its prosecution, including, among other misconduct, Jarom Kesler and Stephen Jensen's burying key prior art references that each of those individuals knew were material to patentability. Specifically, during prosecution of the '911 patent, Jarom Kesler and Stephen Jensen intentionally buried known highly material prior art among voluminous submissions of less relevant and even clearly irrelevant prior art. Jarom Kesler and Stephen Jensen's pattern of misconduct evidenced specific intent to deceive the USPTO, which would not have issued the '911 patent if it had been made properly aware of the buried references.

As discussed below, Jarom Kesler and Stephen Jensen are among the individuals who owed a duty of disclosure to the USPTO during the prosecution of the '911 patent and committed inequitable conduct by breaching that duty of disclosure. Each of these individuals was an attorney of record for prosecuting the application that resulted in the '911 patent.

Jarom Kesler

Jarom Kesler had a duty to disclose information material to the patentability of the '911 patent to the USPTO during prosecution of the '911 patent. Mr. Kesler is a partner at the law firm of Knobbe Martens and an attorney of record for prosecution of the '911 patent who prepared and prosecuted the application resulting in the '911 patent. Among other things, Mr. Kesler signed and filed documents submitted by Masimo during prosecution of the '911 patent, including Masimo's September 22, 2020 Patent Application; September 22, 2020 Certification and Request for Prioritized Examination; September 22, 2020 Information Disclosure Statement; September 22, 2020 Transmittal for Power of Attorney; October 22, 2020 Preliminary Amendment; March 4, 2021 Amendment After Allowance; March 4, 2021 Comments on Reasons for Allowance; and May 25, 2021 Request for Certificate of Correction.

Among other things, Mr. Kesler prepared, signed, and filed Masimo's September 22, 2020 Information Disclosure Statement, which cited no fewer than **1,725** prior art references.

Docket No.: MLR.002C6

Page 1 of 1

INFORMATION DISCLOSURE STATEMENT

First Inventor :	Robert A. Smith
App. No. :	Herewith
Filed :	Herewith
For :	MULTIPLE WAVELENGTH SENSOR EMITTERS
Examiner :	To Be Assigned
Art Unit :	To Be Assigned
Conf. No. :	To Be Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Listed references are of record in U.S. patent application No. 16/437611, filed June 11, 2019, which is relied upon for an earlier filing date under 35 USC 120. Copies of the references are not submitted pursuant to 37 CFR 1.98(d).

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed within three months of the filing date or date of national phase entry, with an RCE or before receipt of a First Office Action after an RCE, and no fee is believed to be required.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 22, 2020

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Registered Practitioner
(949) 760-0404

33555273

(‘911 Prosecution, September 22, 2020 Information Disclosure Statement).

Among other things, Mr. Kesler also prepared, signed, and filed Masimo’s February 14, 2020 Request for Prioritized Examination.

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)			
First Named Inventor:	Robert A. Smith	Nonprovisional Application Number (if known):	
Title of Invention:	MULTIPLE WAVELENGTH SENSOR EMITTERS		
APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.			
<ol style="list-style-type: none"> 1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application. 2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed. 3. The applicable box is checked below: <ol style="list-style-type: none"> I. <input checked="" type="checkbox"/> Original Application (Track One) - Prioritized Examination under § 1.102(e)(1) <ol style="list-style-type: none"> i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web. ---OR--- (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper. ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application. II. <input type="checkbox"/> Request for Continued Examination - Prioritized Examination under § 1.102(e)(2) <ol style="list-style-type: none"> i. A request for continued examination has been filed with, or prior to, this form. ii. If the application is a utility application, this certification and request is being filed via EFS-Web. iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371. iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination. v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2). 			
Signature <u>/Jarom Kesler/</u>		Date <u>2020-09-22</u>	
Name (Print/Typed) <u>Jarom D. Kesler</u>		Practitioner Registration Number <u>57046</u>	
<i>Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*</i>			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

(’911 Prosecution, September 22, 2020 Certification and Request for Prioritized Examination).

Stephen Jensen

Stephen Jensen had a duty to disclose information material to the patentability of the ’911 patent to the USPTO during prosecution of the ’911 patent. As a partner at the law firm of Knobbe Martens, Mr. Jensen was Masimo’s primary outside counsel and an attorney of record for

prosecution of the '911 patent who was substantively involved in the preparation and prosecution of the application that resulted in the '911 patent.

For example, the USPTO expressly lists Mr. Jensen as an attorney of record for prosecution of the '911 patent.

In addition to his own role as an attorney of record for prosecuting the '911 patent, Mr. Jensen—as Masimo's primary outside patent attorney and client liaison—was the Knobbe Martens partner who had ultimate responsibility for and control over Knobbe Martens' legal work for Masimo, including prosecution of the '911 patent. As such, Mr. Jensen had the incentive to, and as discussed below, did in fact prioritize his longstanding loyalties to Masimo over his duties of disclosure to the PTO to facilitate issuance of the '911 patent by committing inequitable conduct.

During prosecution of the '911 patent, Masimo, through its prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, submitted unreasonably voluminous prior art disclosures to obscure four of the most important prior art references, namely U.S. Patent No. 6,816,241 to Grubisic ("Grubisic"), U.S. Patent No. 5,782,756 to Mannheimer ("Mannheimer 756"), U.S. Patent No. 5,638,816 to Kiani et al. ("Kiani 816"), and U.S. Patent No. 5,203,329 to Takatani et al. ("Takatani"). Masimo's prosecution attorneys cited no fewer than 1,748 cited references spanning approximately 65 pages via two information disclosure statements submitted during prosecution. Masimo's September 22, 2020 Information Disclosure Statement, which essentially comprised a document dump of 1,725 references, included numerous clearly irrelevant and (at best) marginally relevant references. Because these references were buried amongst 1,725 disclosed references, the patent examiner could not have considered each of them and, in fact, did not cite them in any office action.

Among the 1,725 cited references was Grubisic. Grubisic relates to the use of LEDs to measure blood parameters and teaches “[a] compact, lightweight instrument for non-invasive blood analyte determination.” Grubisic at Abstract. Grubisic is prior art to the ’911 patent, and at least claim 19 of the ’911 patent is invalid as anticipated by Grubisic under 35 U.S.C. § 102 and as obvious under § 103 in view of Grubisic standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Grubisic discloses every element of at least claim 19 of the ’911 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the ’911 patent.

Masimo’s prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’911 patent, knew during the prosecution of the ’911 patent that Grubisic existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the ’911 patent, as evidenced by the submission of Masimo’s September 22, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Grubisic was material to patentability of the ’911 patent.

Also among the 1,725 cited references was Mannheimer 756. Mannheimer 756 relates to the measurement of blood parameters, and the patent teaches the use of “at least three wavelengths of electromagnetic radiation for determining a blood constituent, such as arterial oxygen saturation, in a patient.” Mannheimer 756 at Abstract. Mannheimer 756 is prior art to the ’911 patent, and at least claim 19 of the ’911 patent is invalid as anticipated by Mannheimer 756 under 35 U.S.C. § 102 and as obvious under § 103 in view of Mannheimer 756 standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Mannheimer 756 discloses every element of at least claim 19 of the ’911 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the ’911 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, knew during the prosecution of the '911 patent that Mannheimer 756 existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '911 patent, as evidenced by the submission of Masimo's September 22, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Mannheimer 756 was material to patentability of the '911 patent.

Also among the 1,725 cited references was Kiani 816. Kiani 816 relates to pulse monitoring and teaches "[a] blood glucose monitoring system . . . which provides for inducing an active pulse in the blood volume of a patient." Kiani 816 at Abstract. Kiani 816 is prior art to the '911 patent, and at least claim 19 of the '911 patent is invalid as anticipated by Kiani 816 under 35 U.S.C. § 102 and as obvious under § 103 in view of Kiani 816 standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Kiani 816 discloses every element of at least claim 19 of the '911 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the '911 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, knew during the prosecution of the '911 patent that Kiani 816 existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the '911 patent, as evidenced by the submission of Masimo's September 22, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Kiani 816 was material to patentability of the '911 patent.

Also among the 1,725 cited references was Takatani. Takatani relates to a pulse oximetry sensor, and Takatani teaches "[a] noninvasive oximeter sensor for controlling and optimizing the

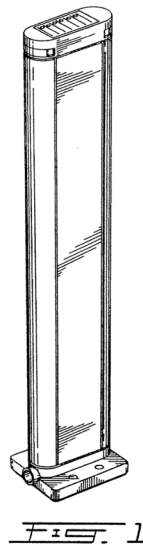
minimum detection depth in the tissue of a patient.” Takatani at Abstract. Takatani is prior art to the ’911 patent, and at least claim 19 of the ’911 patent is invalid as anticipated by Takatani under 35 U.S.C. § 102 and as obvious under § 103 in view of Takatani standing alone, or combined with a person of ordinary skill in the art. As shown in the attached exemplary claim chart, Takatani discloses every element of at least claim 19 of the ’911 patent and otherwise contains disclosures material to the invalidity of the asserted claims of the ’911 patent.

Masimo’s prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’911 patent, knew during the prosecution of the ’911 patent that Takatani existed and that its subject matter and disclosure was closely related and material to the subject matter of the alleged inventions claimed in the ’911 patent, as evidenced by the submission of Masimo’s September 22, 2020 Information Disclosure Statement. At least Kesler and Jensen knew that Takatani was material to patentability of the ’911 patent.

Accordingly, the buried Grubisic reference, Mannheimer 756 reference, Kiani 816 reference, and Takatani reference were, at the very least, highly material to patentability of the alleged inventions claimed in what would become the ’911 patent.

Masimo, through its prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the ’911 patent, submitted two Information Disclosure Statements during prosecution of the patent application that led to the ’911 patent on the following dates: September 22, 2020 and February 9, 2021. These Information Disclosure Statements listed 1,748 prior art references, a substantial number of which were clearly irrelevant or at most minimally relevant to the alleged inventions covered by the pending claims at any point during prosecution.

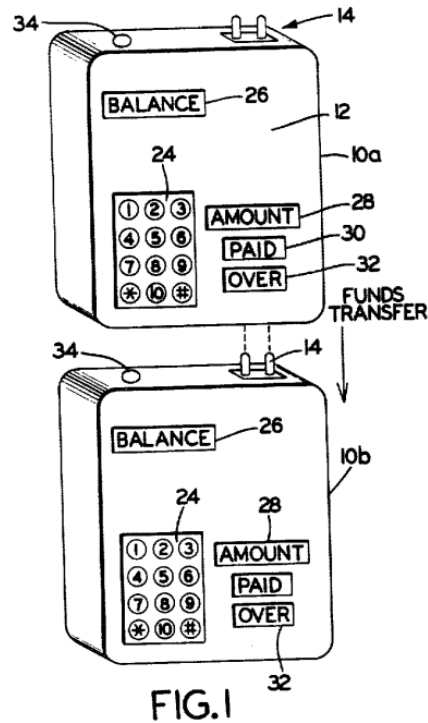
One example of an irrelevant (or at most minimally relevant) submitted reference is U.S. Patent No. Des. 359,546 to Savage et al. (“Savage”), titled “Housing for a dental unit disinfecting device.” Whereas the ’911 patent concerns a physiological monitoring optical sensor, this reference concerns very different subject matter—the ornamental design of a housing for a dental unit disinfecting device. Shown in Figure 1 below is a perspective view of the housing for a dental unit disinfecting device.



This subject matter is far afield from that of the ’911 patent and had the effect of obscuring and thereby burying the most material references, including at least Grubisic, Mannheimer 756, Kiani 816, and Takatani.

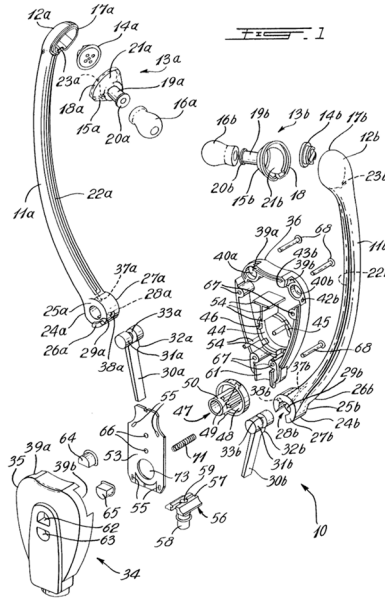
Another example of an irrelevant (or at most minimally relevant) submitted reference is U.S. Patent No. 4,305,059 to Benton (“Benton”), titled “Modular funds transfer system.” Whereas the ’911 patent concerns a physiological monitoring optical sensor, this reference concerns very different subject matter—a system for transferring funds in lieu of cash. For example, the patent discloses that the “invention relates generally to electronic off-line data transfer and more

particularly toward a funds transfer system comprising a plurality of identical hand-held funds data storage and transfer modules for performing cashless transactions without any intervening local or centralized computer.” Benton at 1:5-10. Figure 1 below shows two funds transaction modules.



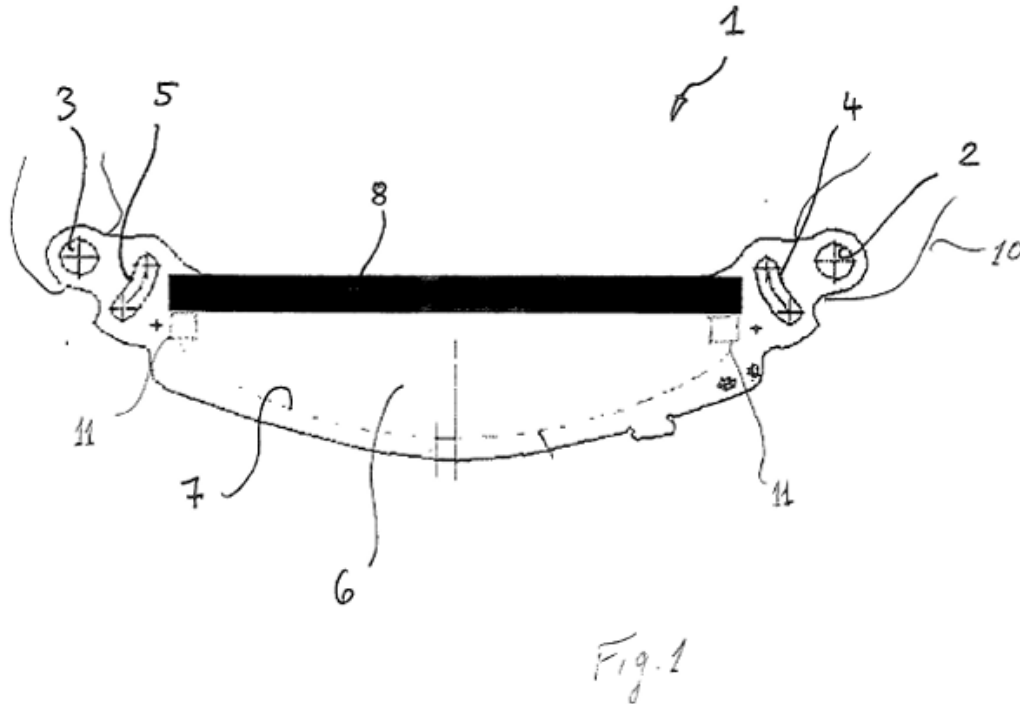
This subject matter is far afield from that of the '911 patent and had the effect of obscuring and thereby burying the most material references, including at least Grubisic, Mannheimer 756, Kiani 816, and Takatani.

Another example of an irrelevant (or at most minimally relevant) submitted reference is U.S. Patent No. 6,595,316 to Cybulski et al. (“Cybulski”), titled “Tension-adjustable mechanism for stethoscope earpieces.” Whereas the '911 patent concerns a physiological monitoring optical sensor, this reference concerns very different subject matter—stethoscope earpieces. For example, the patent discloses a “tension-adjustable headset for [an] electronic stethoscope” Cybulski at 3:42-43. Figure 1 below shows said headset.



This subject matter is far afield from that of the '911 patent and had the effect of obscuring and thereby burying the most material references, including at least Grubisic, Mannheimer 756, Kiani 816, and Takatani.

Another example of an irrelevant (or at most minimally relevant) submitted reference is U.S. Patent Pub. No. 2004/0034898 to Bruegl ("Bruegl"), titled "Self-Tinting Helmet Visor and Method of Making Same." Whereas the '911 patent concerns a physiological monitoring optical sensor, this reference concerns a "Helmet visor with a solar cell device that is arranged directly on the helmet visor, wherein the helmet visor can be darkened or tinted through voltage that is generated by a solar cell device" Bruegl at Abstract. This helmet visor with a solar cell device is shown in Figure 1:



This subject matter is far afield from that of the '911 patent and had the effect of obscuring and thereby burying the most material references, including at least Grubisic, Mannheimer 756, Kiani 816, and Takatani.

During prosecution of the '911 patent, Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent submitted the Information Disclosure Statements, burying the USPTO with at least 1,748 references. Buried in these unreasonably voluminous submissions were the material Grubisic, Mannheimer 756, Kiani 816, and Takatani references. Out of the 1,725 references cited in the September 22, 2020 Information Disclosure Statement, the Grubisic reference was document 1,380, the Mannheimer 756 reference was document 205, the Kiani 816 reference was document 167, and the Takatani reference was document 81.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, were aware of the relevance

and high materiality of Grubisic, Mannheimer 756, Kiani 816, and Takatani. They knew that Grubisic, Mannheimer 756, Kiani 816, and Takatani existed because they included them in an Information Disclosure Statement, and by submitting them in an Information Disclosure Statement, thereby acknowledged their relevance to the prosecution of the application leading to the '911 patent.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, therefore had knowledge of Grubisic, Mannheimer 756, Kiani 816, and Takatani as well as their materiality to patentability, at least giving rise to an inference of intentional breach of their duties of disclosure.

Although Grubisic, Mannheimer 756, Kiani 816, and Takatani were submitted into the file history in the patent application that matured into the '911 patent via citations in the Information Disclosure Statements, these references were buried within a large number of other less relevant or irrelevant documents and were never brought to the examiner's attention.

Notably, despite their knowledge of the contents and materiality of Grubisic, Mannheimer 756, Kiani 816, and Takatani, Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, failed to highlight these references or otherwise distinguish them in any way from the other 1,000-plus cited references at any point during the prosecution of what would become the '911 patent. And Grubisic, Mannheimer 756, Kiani 816, and Takatani are not cumulative of other prior art relied on by the examiner.

Masimo's prosecution attorneys of record Kesler and Jensen, as well as other Masimo agents substantively involved in the prosecution of the '911 patent, thus buried Grubisic, Mannheimer 756, Kiani 816, and Takatani and failed to bring those references to the examiner's

attention to intentionally mislead the examiner in order to improperly procure the '911 patent, notwithstanding that Masimo was not entitled to such patent under 35 U.S.C. §§ 102 and 103.

Masimo's prosecution attorneys of record Kesler and Jensen sought expedited review of the prosecution of the '911 patent while submitting 1,725 prior art references for consideration to the USPTO. By requesting expedited review and submitting 1,725 prior art references for review on a compressed schedule, Masimo's prosecution attorneys of record Kesler and Jensen compounded the USPTO's inability to review the 1,725 prior art references with appropriate scrutiny. On information and belief, this conduct was specifically intended to, and did, obscure material references from the examiner among many minimally relevant references. Therefore, the patent examiner could not possibly have read each reference that Masimo's prosecution attorneys of record had identified. The single most reasonable inference that can be drawn from the evidence is that Masimo's prosecution attorneys of record intended to deceive the USPTO by burying the patent examiner with prior art and leaving the patent examiner with no practical way to review everything that was disclosed or figure out what was pertinent among the 1,725 listed references.

But for this misleading conduct, the examiner would have cited either or all of Grubisic, Mannheimer 756, Kiani 816, and Takatani alone or in combination with other cited references to reject the claims of the '911 patent, including at least claims 1-5, 8, 10-14, 17, 19-25, and 28, as invalid.

Accordingly, the '911 patent is unenforceable due to inequitable conduct.

The effect of Kesler and Jensen's conduct is not limited to the '911 patent. All subsequent "child" or other related patents that are based on the same specification or relevant portions thereof are tainted by Masimo's inequitable conduct and, therefore, are also unenforceable under the doctrine of infectious unenforceability.

Dated: August 2, 2023

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Attorneys for Plaintiff, Apple Inc.

CERTIFICATE OF SERVICE

I, Jamie L. Kringstein, hereby certify that on August 2, 2023, a copy of the foregoing document was served on all counsel of record via email as follows:

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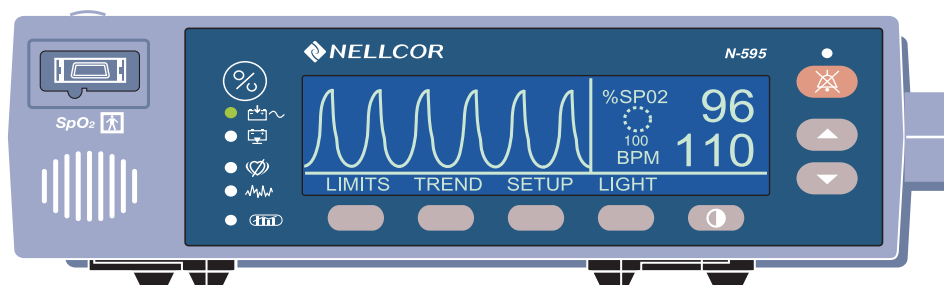
/s/ Jamie L. Kringstein

EXHIBIT 2



OxiMAX N-595

Pulse Oximeter Operator's Manual



Nellcor Puritan Bennett Inc. is an affiliate of Tyco Healthcare. *Nellcor*, *Oxiband*, *Durasensor*, *OxiCliq*, *Dura-Y*, *MAX-FAST*, and *OxiMAX* are trademarks of Nellcor Puritan Bennett Inc.

This ISM device complies with Canadian ICES-001.

Cet appareil ISM est conforme à la norme NMB-001 Canada.

To obtain information about a warranty, if any, contact Nellcor's Technical Services Department, or your local representative.

Purchase of this instrument confers no express or implied license under any Nellcor Puritan Bennett patent to use the instrument with any sensor that is not manufactured or licensed by Nellcor Puritan Bennett.

Covered by one or more of the following U.S. Patents and foreign equivalents: 4,621,643; 4,653,498; 4,700,708; 4,770,179; Re. 35,122; 4,802,486; 4,869,254; 4,928,692; 4,934,372; 5,078,136; 5,351,685; 5,368,026; 5,485,847; 5,533,507; 5,662,106; and 5,853,364.

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Safety Information

Warnings



Warnings are identified by the WARNING symbol shown above.

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.



WARNING: The sensor extrapolates from the date and time provided by the N-595 when recording the sensor event record to the sensor. The accuracy of the date/time is the responsibility of the N-595. It is recommended that the N-595 user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.



WARNING: Explosion hazard. Do not use the N-595 pulse oximeter in the presence of flammable anesthetics or gases.



WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a pulse oximeter with a broken display panel.



WARNING: Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, *OxIMAX* sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.



WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity and inaccurate readings of the N-595 pulse oximeter.



WARNING: Failure to cover the *OxIMAX* sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

Cautions



Cautions are identified by the CAUTION symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of the N-595 pulse oximeter.



Caution: When connecting the N-595 to any instrument, verify proper operation before clinical use. Both the N-595 and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the pulse oximeter's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port (N-595 data port connector) configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2. The N-595 accuracy may degrade if it is connected to secondary I/O devices when the instrument is not connected to earth reference.



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



Caution: Dispose of battery in accordance with local requirements and regulations.

Introduction



WARNING: The N-595 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Intended Use for the N-595

The N-595 pulse oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The N-595 is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only.

Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Home Care use is defined as managed/used by a lay person (parent or other similar non-critical caregiver) in the home environment.

Use with any particular patient requires the selection of an appropriate oxygen *OxiMax* sensors as described in this Operator's Manual.

Motion performance claims are applicable to models MAX-A, MAX-AL, MAX-P, MAX-N, and MAX-I Nellcor *OxiMAX*TM oximetry sensors.

How to Use this Manual

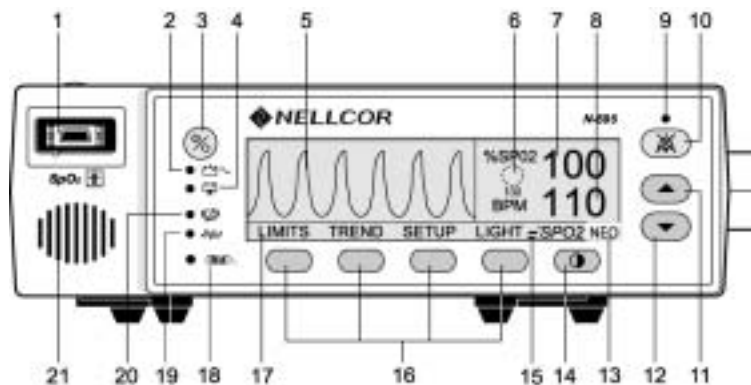
All users should read this manual thoroughly. More experienced users of the N-595 will be able to go to the topics for the information they require.

The current copy of this manual is available on the internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Description of Controls, Indicators, and Symbols

Identification of Front Panel Buttons and Symbols

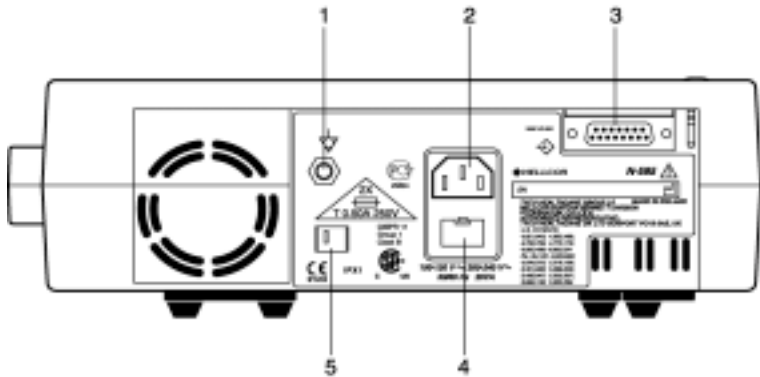


Using the
N-595

1. SpO2 <i>OxiMAX</i> Sensor Port, page 19	12. ADJUST DOWN Button, page 10
2. AC Power Indicator, page 12	13. Neonate Mode Indicator, page 13
3. ON/STANDBY Button, page 9	14. CONTRAST Button, page 10
4. Low Battery Indicator, page 12	15. Fast Response Mode Indicator, page 13
5. Waveform Display, page 10	16. Softkeys, page 10
6. <i>SatSeconds</i> TM Indicator, page 13	17. Menu Bar, page 10
7. %SpO2 Display, page 12	18. Data In Sensor Indicator, page 13
8. Pulse Rate Display, page 12	19. Motion Indicator, page 12
9. Alarm Silence Indicator, page 12	20. Pulse Search Indicator, page 13
10. ALARM SILENCE Button, page 9	21. Speaker
11. ADJUST UP Button, page 10	

Figure 1: Front Panel Buttons and Symbols

Identification of Rear Panel Components

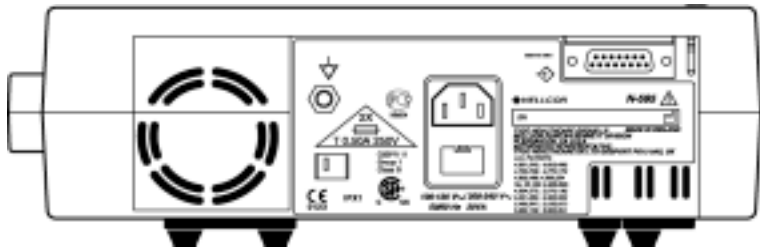


1. Equipotential Terminal (Ground)	4. Fuse Holder
2. AC Power Connector, page 17	5. Supply Voltage Selector Switch, page 17
3. Data Port Connector, page 91	

Figure 2: Rear Panel Components

N-595 Symbols




The symbols that are located on the rear panel of the N-595 are as follows:



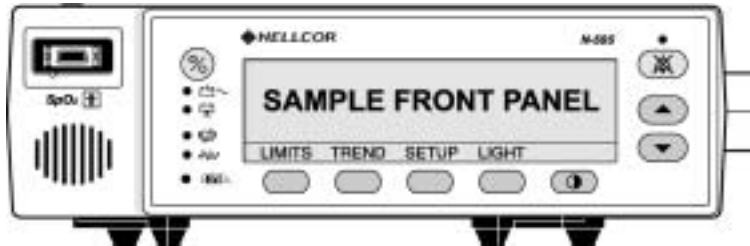
See Instructions for Use




Fuse Replacement

-  Equipotential Terminal (ground)
-  Date of Manufacture
-  Data Interface

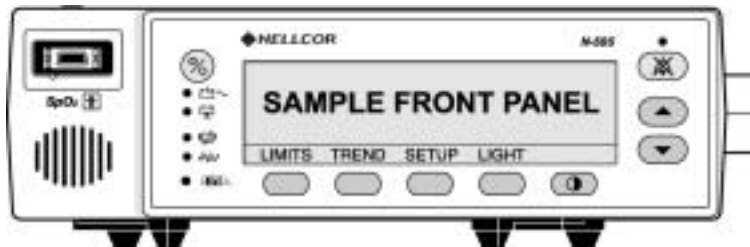
There is one symbol located on the front panel of the N-595.





Using the
N-595

-  Type BF Applied Part - Not defibrillator proof.

Description of Controls



Note: A button press, except the ON/STANDBY button, should result in either a valid or an invalid key tone (refer to Table 1 on page 14). If the key pressed fails to emit a tone, contact qualified service personnel.

-  The ON/STANDBY button. Used to turn the N-595 monitor on or off.
-  The ALARM SILENCE button. Used to silence current alarms for the alarm silence duration period. When an alarm has been silenced, pressing the button again reactivates, or “unsilences” the alarm. It is also used to view and adjust alarm silence duration and alarm volume.



The ALARM SILENCE button clears “SENSOR OFF,” “LOW BATTERY,” and “SENSOR DISCONNECT” messages from the display.



The ADJUST UP button. Used to increase variable parameters of the monitor.



The ADJUST DOWN button. Used to decrease variable parameters in the monitor.



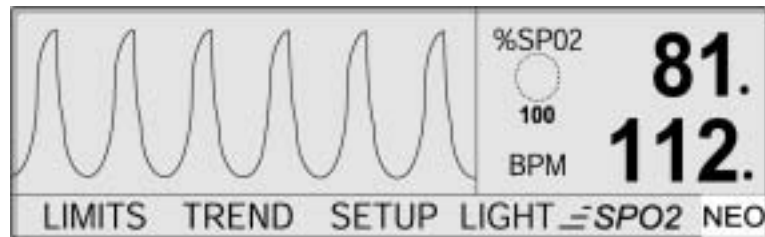
The CONTRAST button. Used in conjunction with the ADJUST UP and ADJUST DOWN buttons to lighten or darken the display screen.



The softkey buttons have multiple uses depending on the legend displayed above the button.

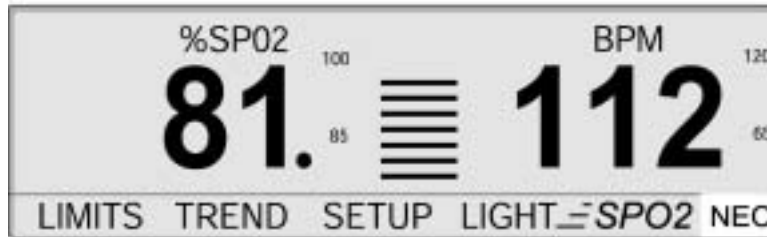
Description of Displays and Indicators

The type of display is user selectable. Refer to *Selecting the Pleth View* on page 34.



The pleth display includes a “wiper bar” plethysmographic waveform, menu bar, and current measured %SpO₂ and pulse rate. If *SatSeconds* are enabled, the pleth display includes the *SatSeconds* indicator and *SatSeconds* setting. A decimal point after the %SpO₂ or

pulse rate indicate that the respective limits have been changed from the power on defaults (*Monitor Trend Data* on page 53).



The blip display includes a pulse amplitude blip bar, current measured %SpO₂ and pulse rate, and current upper and lower %SpO₂ and pulse rate limits. If *SatSeconds* are enabled, the blip display includes the *SatSeconds* indicator and *SatSeconds* setting. Decimal points after the %SpO₂ or pulse rate indicate that the respective limits have been changed from the power-on defaults.

There are various matrixes within the OxiMAX algorithm. Some of these, are used to assess the severity of conditions presented to the N-595 in measuring SpO₂ and pulse rate on a patient. These individual matrices or combinations of these matrices are used to drive the LED indicators on the N-595 front panel.

The *OxiMax* algorithm automatically extends the amount of data required for measuring SpO₂ and pulse rate depending on the measurement conditions. During normal measurement conditions the averaging time is 6-7 seconds. During challenging measurement conditions which could be caused by low perfusion, motion, external interference like ambient light, or a combination of these, the OXIMAX algorithm automatically extends the amount of data required beyond 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO₂ and Pulse Rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO₂ and pulse rate displays flash zeros indicating a loss-of-pulse condition.



WARNING: Failure to cover the *OxiMAX* sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.



%SpO2

81

The %SpO2 Display. Shows the hemoglobin oxygen saturation level. The display value flashes zeros during loss-of-pulse alarms and flashes the SpO2 value when the SpO2 is outside the alarm limits. During Pulse Search, the monitor continues to update the display. If alarm limits have been changed from their power-on defaults, a decimal point (.) is displayed after the SpO2 value (81.).



The Pulse Amplitude Indicator (blip bar). Indicates pulse beat and shows the relative pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse. This indicator is available only in the blip view.

BPM

112

The Pulse Rate Display. Shows the pulse rate in beats per minute. It flashes during loss-of-pulse alarms and when the pulse rate is outside of the alarm limits. During Pulse Search, the monitor continues to update the display. Pulse rates outside of the pulse rate range (20 to 250 bpm) are displayed as the closest value within the range. If alarm limits have been changed from their power-on defaults, a decimal point (.) is displayed after the BPM value (112.).



The AC Power Indicator. Lights continuously when the N-595 is connected to AC power. It also indicates that the battery is charging. It is off when the monitor is being powered by internal battery.



The Low Battery Indicator. Lights continuously when 15 or fewer minutes of battery capacity remain. Flashes when the battery capacity reaches critical condition.



The Alarm Silence Indicator. Lights continuously when an audible alarm has been silenced. It flashes when the alarm silence duration has been set to Off.



The Motion Indicator. The motion indicator is lit whenever the *OxiMAX* algorithm detects the presence of artifacts¹ independent of its severity or the impact on the SpO2 or pulse rate values. When the

motion indicator and the pulse search indicator are simultaneously lit, it is an indication that the artifact is significant and/or has been persistent.



The Pulse Search Indicator. Lights continuously prior to initial acquisition of a pulse signal and during prolonged and challenging monitoring conditions. The pulse search indicator flashes during a loss-of-pulse signal.



The Data In-Sensor Indicator. Lights to indicate that the attached *OxiMAX* sensor contains a patient sensor event record. The sensor event record information may be viewed or printed.



The *SatSeconds* Indicator. Fills in clockwise as the *SatSeconds* alarm management system detects a %SpO₂ reading outside of the limit setting. Empties in counterclockwise direction when %SpO₂ reading is within limits. When the indicator is full, a medium priority alarm will sound.



The Fast Response Mode Indicator. The response mode setting dictates the response time (2 to 4 seconds in fast mode and 4 to 7 seconds in normal mode) applied by the *OxiMAX* algorithm in its calculation of SpO₂. The *OxiMAX* algorithm's calculation of pulse rate is unaffected by the response mode setting. The trending interval (2-seconds or 4-seconds) is updated automatically by the monitor to roughly correspond with the SpO₂ calculation response time.



The Neonate Alarm Limits Indicator. This symbol is displayed when the alarm limits are set to neonate. No symbol is displayed when the monitor is set to adult limits.



¹ Artifacts are events contained in the in-sensor data.

Description of Audible Indicators

Table 1 identifies the audible indicators of the N-595 indicators.

Table 1: Audible Indicators

Function	Description
Alarm Silence Reminder	Three beeps that sound approximately every 3 minutes when alarms are silenced with the alarm silence duration set to Off and the alarm silence reminder function is enabled.
Confirmation Tone	Three beeps sound to indicate that default settings have been saved or reset to factory defaults or trend data has been deleted.
Invalid Button Press	A short, low-pitched tone indicating that a button has been pressed that is not appropriate for the current state of the monitor.
Valid Button Press	A short, medium-pitched tone indicating that an appropriate button has been pressed.
High Priority Alarm	A high-pitched, fast-pulsing tone indicating loss-of-pulse.
Medium Priority Alarm	A medium-pitched, pulsing tone indicating an SpO2 or pulse rate limit violation.
Low Priority Alarm	A low-pitched, slow-pulsing tone indicating an <i>OxiMAX</i> sensor disconnect, low battery, or monitor failure.
Power-On Self-Test Pass	A 1-second tone indicating that the N-595 has been turned on and has successfully completed the power-on self-test.
Pulse Beep	A single beep sounds for each detected pulse. The pitch of the pulse beep signal changes with a point-by-point rise or fall in the saturation level.
Volume Setting Tone	A continuous tone that is used when adjusting the alarm volume.

Using the
N-595

Setting up the Monitor



WARNING: To ensure patient safety, do not place the pulse oximeter in any position that might cause it to fall on the patient.



WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.



WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.



WARNING: Disconnect the N-595 and Nellcor *OxIMAX* sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.



WARNING: To ensure accurate performance and prevent device failure, do not subject the N-595 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.



WARNING: Do not use an N-595 pulse oximeter, *OxIMAX* sensor, cables, or connectors that appear damaged.



WARNING: Do not lift the pulse oximeter by the pulse oximetry cable or power cord because the cable or cord could disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

Using the
N-595

Using the
N-595



WARNING: The N-595 is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during the defibrillation and shortly thereafter.



WARNING: In the USA, do not connect the pulse oximeter to an electrical outlet controlled by a wall switch, because the pulse oximeter may be accidentally turned off.



WARNING: Use only the Nellcor pulse oximetry cable DOC-10 with the N-595 pulse oximeter. Use of another pulse oximetry cable will have an adverse effect on performance. Do not attach any cable that is intended for computer use to the *OxIMAX* sensor port. Do not connect any device other than a Nellcor-approved *OxIMAX* sensor to the *OxIMAX* sensor connector.



WARNING: The N-595 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the N-595 should be observed to verify normal operation in the configuration it is to be used.

List of Components

Quantity	Item
1	N-595 Pulse Oximeter
1	Nellcor <i>OxiMAX</i> Sensor or Assortment Pack
1	DOC-10 Pulse Oximetry Cable
1	N-595 Operator's Manual (applicable to country of sale) and/or Compact Disk
1	Power Cord (applicable to country of sale)
2	Fuses, 0.5 A, 250 volts, slow-blow, IEC (5 x 20 mm)
1	Sensor Accuracy Grid
1	Quick Guide

Using the
N-595

Connecting the N-595 to AC Power



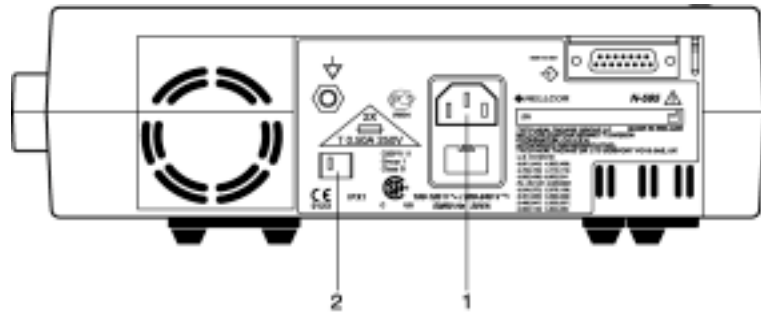
WARNING: In the USA, do not connect the pulse oximeter to an electrical outlet controlled by a wall switch, because the pulse oximeter may be accidentally turned off.



Caution: The SUPPLY VOLTAGE SELECTOR switch must be set to the correct voltage (115 or 230) to avoid equipment damage and ensure battery charging.



Caution: Use only the hospital-grade power cord provided by Nellcor.



1. Power Connector 2. Supply Voltage Selector

1. Set the SUPPLY VOLTAGE SELECTOR (2) switch to the applicable voltage.
2. Plug the female connector end of the power cord into the N-595 POWER CONNECTOR (1) on the rear of the monitor.
3. Plug the male connector of the power cord into a properly grounded AC outlet.



4. Verify that the monitor's AC POWER INDICATOR is lit.

Note: If the AC POWER INDICATOR is not lit, check:

- the power cord
- the SUPPLY VOLTAGE SELECTOR switch
- the user-accessible fuses
- the AC power outlet

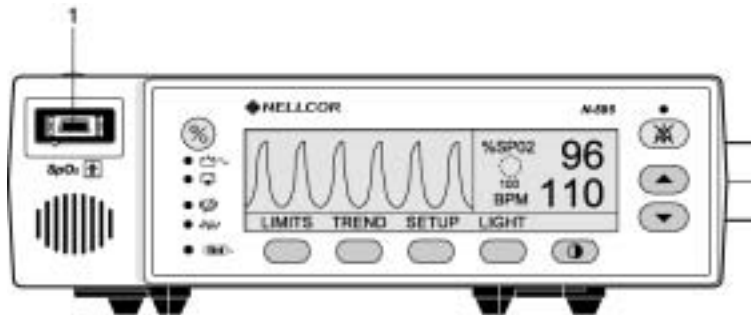
Connecting an *OxiMAX* Sensor to the N-595

The *OxiMAX* sensor type is displayed at the bottom of the display when an *OxiMAX* sensor is connected to the N-595 or when the N-595 completes POST with an *OxiMAX* sensor attached.



Caution: Use only Nellcor-approved *OxiMAX* sensors and pulse oximetry cables.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents, such as nail polish, dye, or pigmented cream.



1. SpO2 *OxiMAX* Sensor Port

1. Connect a DOC-10 pulse oximetry cable to the SpO2 *OxiMAX* sensor port (1) of the monitor.
2. Connect a Nellcor *OxiMAX* SpO2 sensor to the other end of the DOC-10 pulse oximetry cable.

Battery Operation



WARNING: Dispose of battery in accordance with local requirements and regulations.

Operating the N-595 on Battery Power

The N-595 monitor has an internal battery that can be used to power the monitor during transport or when AC power is not available. A new, fully charged battery will provide at least 2 hours of monitoring time under the following conditions:

- No audible alarms sound
- No analog or serial output devices are attached to the N-595

The monitor cannot operate with a fully discharged battery. Before attempting to turn on an N-595 monitor whose battery charge has been completely depleted, first plug the monitor into an AC outlet to allow the battery to charge for a few minutes. The monitor may then be powered on.

To charge a low or dead battery, connect the monitor to AC power. A full charge of a dead battery takes 14 hours while the monitor is turned off. A full charge of a dead battery takes 18 hours while the monitor is in operation (monitoring a patient).

When all of the following conditions are present for 15 minutes, the N-595 will automatically shut down:

- Monitor is running on battery power
- No buttons have been pressed

Using the
N-595

- No pulse has been detected (for example, when a patient is not connected to the *OxiMAX* sensor or the *OxiMAX* sensor is disconnected from the monitor)
- No alarms are present (other than low battery or a non-correctable error)

Note: Whenever the monitor is connected to AC power, the battery is being charged. Therefore, it is recommended that the monitor remain connected to AC power when not in use. This will ensure a fully charged battery whenever it is needed.

Using the
N-595

Low Battery Indicator

The Low Battery Indicator lights and a low priority alarm begins to sound when approximately 15 minutes of monitoring time is available on the existing battery charge. Refer to Table 2 for a description of the low and critical battery conditions.

If the monitor is not on AC power, a low battery audible alarm can be canceled by pressing the ALARM SILENCE button. The low battery indicator and display screen message will continue to be displayed. Plugging the monitor into AC power will silence the audible alarm, but the low battery indicator will stay lit as long as the battery is in the low voltage condition. After the 15-minute period of low battery condition, a high priority alarm will sound for about 10 seconds before the monitor shuts off.

If the monitor backlight is turned off during a low battery condition, the backlight cannot be turned back on.

It is recommended that qualified service personnel replace the internal battery every 24 months. Replaced batteries should be disposed of in accordance with local ordinances.



Caution: If the N-595 pulse oximeter is to be stored for a period of 3 months or longer, notify service personnel to remove the battery from the pulse oximeter prior to storage. Recharge the battery when the battery has not been charged for 2 or more months.



Caution: The pulse oximeter default settings will return to factory default setting if the battery becomes fully discharged or is replaced. Qualified service personnel will have to reset the institutional defaults, following the instructions in the service manual.

Note: If the AC voltage selector switch on the monitor rear panel does not match your AC voltage source, the monitor may run on battery power, even though it is plugged into AC power, which will eventually result in a low priority alarm and a lighted low battery indicator. Ensure that the switch setting matches your AC voltage.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter.

Table 2: Low Battery and Critical Battery

State	Critical Battery	Low Battery	AC	Operation
1	No	No	Yes	SpO2- normal AC/Battery charge LED-on LOW BATTERY LED-off LOW BATTERY message-off Audible alarm-off Error code-none Effect of ALARM SILENCE key-normal Shutdown-N/A



Table 2: Low Battery and Critical Battery

State	Critical Battery	Low Battery	AC	Operation
2	No	No	No	<p>SpO2-normal</p> <p>AC/Battery charge LED-off</p> <p>LOW BATTERY LED-off</p> <p>LOW BATTERY message-off</p> <p>Audible alarm-off</p> <p>Error code-none</p> <p>Effect of ALARM SILENCE key-normal</p> <p>Shutdown- N/A</p>
3	No	Yes	No	<p>SpO2-normal</p> <p>AC/Battery charge LED-off</p> <p>LOW BATTERY LED-on</p> <p>LOW BATTERY message-on</p> <p>Audible alarm-low priority</p> <p>Error code-logged</p> <p>Effect of ALARM SILENCE key-First press silences audio alarm, second press cancels LOW BATTERY message (LED) stays on until Low Battery Condition is corrected.</p> <p>Shutdown-N/A</p>

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Table 2: Low Battery and Critical Battery

State	Critical Battery	Low Battery	AC	Operation
4	No	Yes	Yes	<p>SpO2-normal</p> <p>AC/Battery charge LED-on</p> <p>LOW BATTERY LED-on</p> <p>LOW BATTERY message-off</p> <p>Audible alarm-off</p> <p>Error code-logged</p> <p>Effect of ALARM SILENCE key-N/A (LED stays on)</p> <p>Shutdown-N/A</p> <p>Note: Connecting AC functions the same as ALARM SILENCE key in state 3.</p>
5	Not used			
6	Yes	Yes	No	<p>SpO2-not displayed</p> <p>AC/Battery charge LED-off</p> <p>LOW BATTERY LED-on (flashing)</p> <p>LOW BATTERY message-on</p> <p>Audible alarm-high priority</p> <p>Error code-displayed and logged</p> <p>Effect of ALARM SILENCE key-none</p> <p>Shutdown-after 10 seconds</p>

Using the
N-595

Table 2: Low Battery and Critical Battery

State	Critical Battery	Low Battery	AC	Operation
7	Yes	Yes	Yes	<p>SpO2-not displayed</p> <p>AC/Battery charge LED-on</p> <p>LOW BATTERY LED-on (flashing)</p> <p>LOW BATTERY message-on</p> <p>Audible alarm-high priority</p> <p>Error code-displayed and logged</p> <p>Effect of ALARM SILENCE key-N/A</p> <p>Shutdown-after 10 seconds</p>

Using the
N-595

Using the Monitor

Introduction

The parameters of the N-595 monitor are preset to factory default settings. See *Factory Defaults* on page 139. The factory default parameters may be changed to institutional default parameters by following the procedures in the N-595 service manual.

Table 3 lists the parameters, ranges available, and the factory default setting. The parameters may be set on an individual basis, by the clinician, and these settings will remain in effect until the N-595 is turned off.

Table 3: Parameter Ranges

Parameter	Ranges/ Selections	Factory Adult Defaults	Factory Neonate Defaults
%SpO2 Upper Alarm Limit	Lower Alarm Limit plus 1 to 100%	100%	95%
%SpO2 Lower Alarm Limit	20% to Upper Alarm Limit minus 1	85%	80%
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	170 bpm	190 bpm
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40 bpm	90 bpm
Alarm Silence Duration	Alarms 30, 60, 90, 120 seconds	60	60
Alarm Volume	1 to 10	7	7

Table 3: Parameter Ranges

Parameter	Ranges/ Selections	Factory Adult Defaults	Factory Neonate Defaults
Alarms	Allow Off - Yes/No	Yes	Yes
	Off Reminder - Yes/No	Yes	Yes
Data Port Baud Rate	2400, 9600, 19200	9600	9600
Data Port Mode	ASCII, GRAPH, OXINET, CLINICAL, AGILENT (HP Agilent), SPACELBS, MARQ (GE Marquette), DATEX (Datex- Ohmeda)	ASCII	ASCII
Default Display Format	Pleth, Blip	Pleth	Pleth
Default Trend Display	Saturation, Pulse Rate, Dual, Histogram	Saturation	Saturation
Display Contrast	Low to high	Medium	Medium
Language	English, French, German, Dutch, Portuguese, Spanish, Italian, Swedish	English	English
Limits	Adult, Neonate	Adult	Neonate
Pulse Beep Volume	0 to 10	4	4
Response Mode	Normal or Fast	Normal	Normal

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N-595

Table 3: Parameter Ranges

Parameter	Ranges/ Selections	Factory Adult Defaults	Factory Neonate Defaults
RS-232 Level Nurse Call Polarity	Normally High, Normally Low	Normally low	Normally low
<i>SatSeconds</i>	Off, 10, 25, 50, 100	Off	Off
Sensor Event Date Format (SENSOR-R and SENSOR-RW	SpO2, SpO2+Pulse Rate, Default (default is factory default)	Default	Default
Sensor Messages Enabled	Yes, No	Yes	Yes
Trend Display	Dual, %SpO2, Pulse, Histogram, Amplitude	%SpO2	%SpO2
Trend Scale	48, 36, 12.8, 4, 2, 1 hours, 30, 15 minutes, 40, 20 seconds	2 hours	2 hours



Turning On the Monitor

Before using the N-595 in a clinical setting, you must verify that the monitor is working properly and is safe to use. Proper working condition will be verified each time the N-595 is turned on as described in the following procedure.



Caution: If any indicator or display element does not light when the pulse oximeter is turned on, do not use the pulse oximeter. Instead, contact qualified service personnel, your local Nellcor representative, or Nellcor's Technical Services Department.



Note: Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display measurements, include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

Note: The monitor automatically starts the Power-On Self-Test (POST), which tests the monitor circuitry and functions.



Caution: During POST (immediately after power-up), confirm that all indicators light, all display segments turn on, and the pulse oximeter speaker sounds a one-second tone.



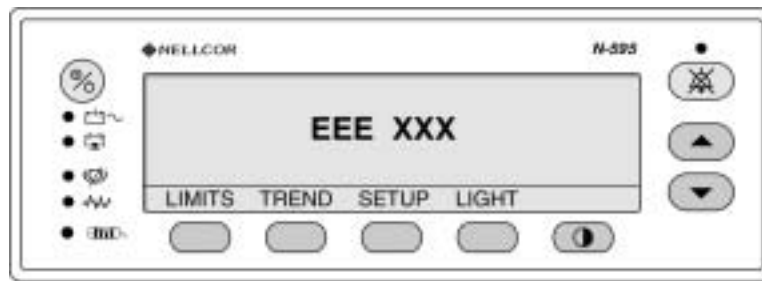
1. Turn on the N-595 by pressing the ON/STANDBY button.
2. Ensure that all of the front panel indicators illuminate.
3. Once the display test portion of POST is complete, the N-595 software version is displayed for approximately 5 seconds.



Note: The software version shown above is only a sample. Check your monitor for the software version installed.

Software version numbers are often needed when calling Nellcor's Technical Services Department or your local Nellcor representative for technical assistance. Write down the software version number and have it available prior to requesting technical assistance.

4. If the N-595 detects an internal problem during POST, an error tone sounds and the monitor displays an error code (EEE) and the corresponding number (see *Troubleshooting* on page 117).



5. Upon successful completion of the POST, the N-595 sounds a one-second tone indicating that the monitor has passed the test.



WARNING: If you do not hear the POST pass tone, do not use the pulse oximeter.



WARNING: Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm tone.

Note: In addition to serving as the POST pass verification, the POST pass tone also functions as an audible confirmation that the speaker is performing properly. If the speaker does not function, the alarm warning sounds cannot be heard.

***OxiMAX* Sensor Attached**

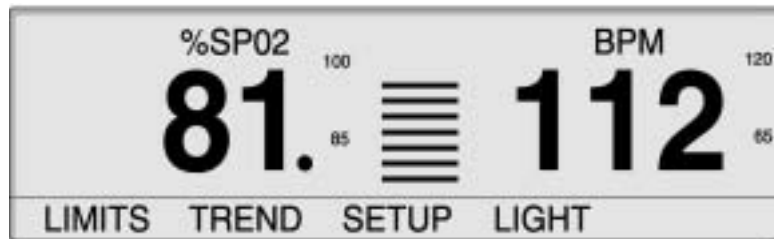
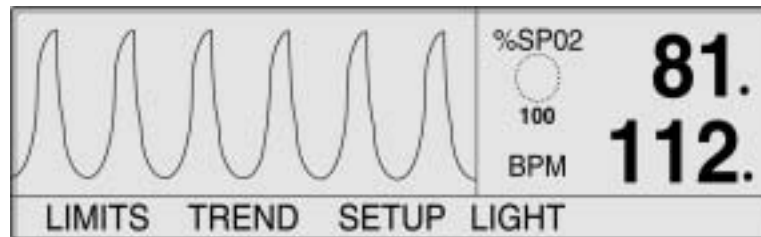
When an *OxiMAX* sensor is attached to the monitor, a “DATA TYPE: . . .” message is displayed briefly at the bottom of the monitor display. For a sensor containing data, the message identifies the sensor data type. For a blank sensor, the message identifies the monitor’s current

data type setting that will be used to write data to the sensor. The data type settings are SPO2 and SPO2+BPM.

Note: The type of data recorded is only displayed when data is resent in the *OxiMAX* sensor.

The monitor displays zeros in the %SpO2 and Pulse Rate displays while the N-595 is searching for a valid pulse. For optimal performance, allow the monitor to search and lock onto a pulse for approximately 10 seconds in non-motion conditions.

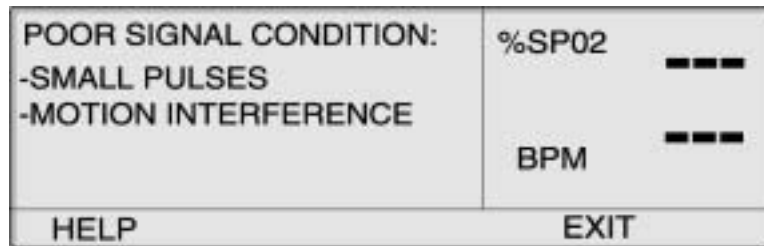
When a valid pulse is detected, the monitor enters the Monitoring Mode and displays patient parameters.



Look for movement of the blip bar or of the plethysmographic waveform indicating that the monitor is displaying real-time data. Listen for the pulse beep tone. If the pulse beep tone does not sound with each pulse, it is an indication that the pulse beep volume is set to zero, the speaker is malfunctioning, or the signal is corrupted.

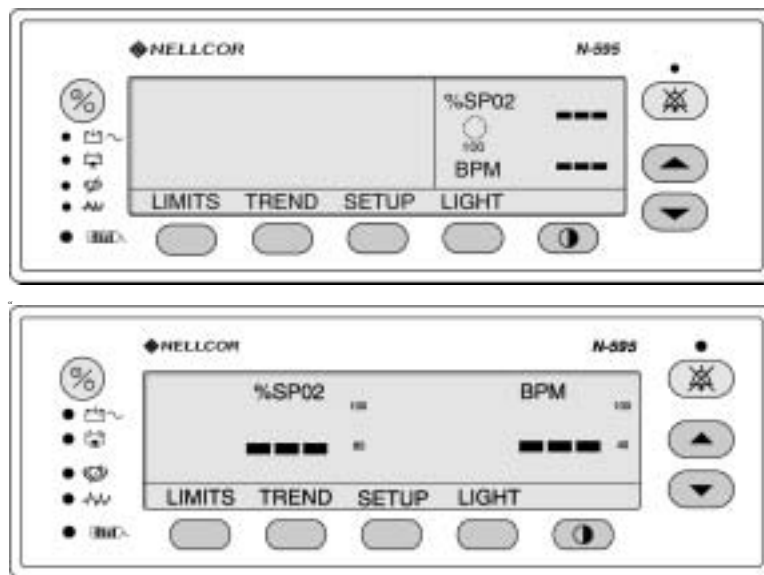
When an *OxiMAX* sensor is attached to the monitor and is applied to a patient, if the monitor loses the pulse signal, the monitor will display “--- & ---” (3 dashes and 3 dashes) and remain in Pulse Search Mode for 5 seconds before displaying the poor signal condition screen. The poor signal condition screen is part of the N-595's Sensor Messages

feature. For more information about *OxiMAX* Sensor Messages, refer *OxiMAX Sensor Messages* on page 49.



No *OxiMAX* Sensor Attached

Upon successful completion of the POST, the N-595 monitor sounds a one-second tone indicating that the monitor has passed POST.



The monitor displays dashes (---) and the Pulse Search indicator is not lit, indicating that the monitor failed to detect an *OxiMAX* sensor.

Turning the Backlight On or Off

Note: When the backlight is off, any of the following conditions will turn on the backlight:

- pressing any of the softkeys
- pressing the CONTRAST button
- pressing the ALARM SILENCE button
- any alarm



LIGHT



With the monitor in the normal monitoring mode, press the LIGHT softkey.

Adjusting Screen Contrast

With the monitor in the normal monitoring mode:



1. Press the CONTRAST button.



2. Press the ADJUST UP or ADJUST DOWN button until the desired contrast is obtained.



3. Press the CONTRAST button.

Selecting the Pleth View

The pleth view displays the pleth waveform, %SpO₂, and pulse rate data. Refer to *Principles of Operation* on page 143, for a description of the pleth waveform.

With the monitor in the normal monitoring mode:

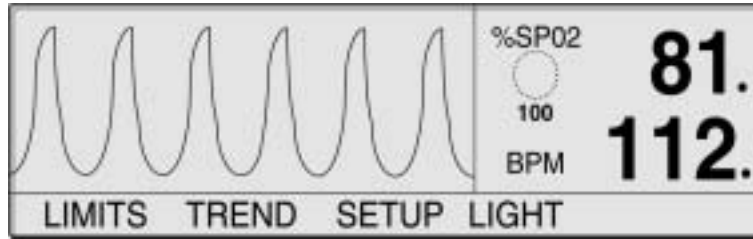
- SETUP** 1. Press the SETUP softkey.



- VIEW** 2. Press the VIEW softkey.



- PLETH** 3. Press the PLETH softkey.



Using the
N-595

Selecting the Blip View

Displays SpO₂, pulse rate, blip bar, and limits in a larger format for easier viewing.

With the monitor in the normal monitoring mode:

- SETUP** 1. Press the SETUP softkey.

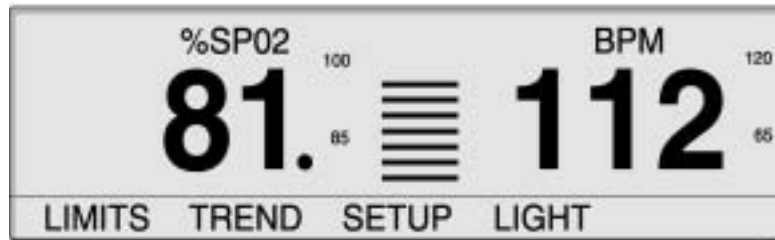


- VIEW** 2. Press the VIEW softkey.



3. Press the BLIP softkey.

BLIP



Using the
N-595

Setting the Pulse Beep Volume

With the monitor in the normal monitoring mode:



1. Press and hold the ADJUST UP/ADJUST DOWN button to increase/decrease pulse beep volume.

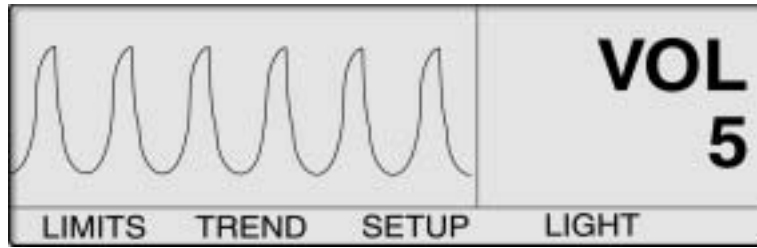
Setting the Alarm Volume

The Alarm Volume display allows the user to adjust the volume of alarm tones.

With the monitor in the normal monitoring mode:



1. Press the ALARM SILENCE button until the alarm volume level is displayed and sounds on the monitor.



2. While continuing to press the ALARM SILENCE button, press and hold the ADJUST UP/ADJUST DOWN button to increase/decrease the volume.



Setting the Date and Time



WARNING: The sensor extrapolates from the date and time provided by the N-595 when recording the sensor event record to the sensor. The accuracy of the date/time is the responsibility of the N-595. It is recommended that the N-595 user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

With the monitor in the normal monitoring mode:

SETUP



1. Press the SETUP softkey.



NEXT 2. Press the NEXT softkey.



CLOCK 3. Press the CLOCK softkey.



SET 4. Press the SET softkey.



5. Press the SELECT softkey to select:

TIME HOURS : MINUTES : SECONDS (16:46:05)

DATE DAY - MONTH - YEAR (30-JAN-02)

TIME 16 : 46 : 05		%SP02 100
DATE 30 - JAN - 02		BPM 59.
SELECT	BACK	EXIT



6. Use the ADJUST UP or ADJUST DOWN buttons to change the selected value.



EXIT 7. Press the EXIT softkey.



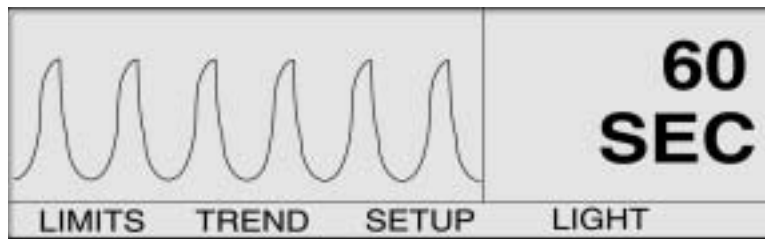
Setting Alarm Silence Duration

The Alarm Silence Duration display allows the user to adjust the alarm silence duration.

With the monitor in the normal monitoring mode:



1. Press the ALARM SILENCE button until the alarm silence duration setting is displayed. Alarm silence durations that are available are OFF, 30, 60, 90, and 120 seconds.



2. Press and hold the ALARM SILENCE button and the ADJUST UP button to increase the alarm silence duration setting.



3. Press and hold the ALARM SILENCE button and the ADJUST DOWN button to decrease the alarm silence duration setting.

Note: Releasing the ADJUST UP or ADJUST DOWN button sets the alarm silence duration.

Disabling Audible Alarms

Setting the alarm silence duration to OFF means that the monitor will produce no audible alarms.

Note: The ability to set the alarm silence duration to OFF can be enabled or disabled by qualified service personnel as described in the service manual. The current copy of the service manual is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_SuppProductManuals.html



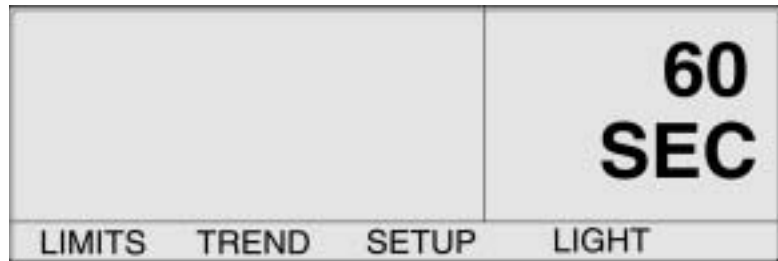
WARNING: Do not silence the audible alarm function or decrease the audible alarm volume if patient safety could be compromised.



With the monitor in the normal monitoring mode:



1. Press the ALARM SILENCE button until the alarm silence duration setting is displayed.



2. While pressing the ALARM SILENCE button, press and hold the ADJUST UP button until OFF is displayed. Release the buttons.





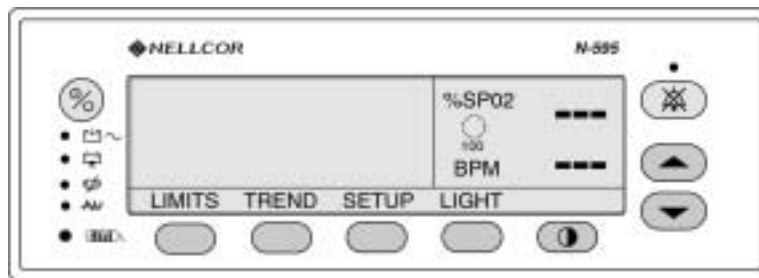
Selecting Standby Mode

The standby mode allows the monitor to retain the alarm limit settings that are in effect while monitoring a patient. The monitor must be powered by AC power to enter the standby mode.

Usually the standby mode is used when a patient has to leave the monitor for a period of time and will return to the same monitor.

To place a monitor in the standby mode:

1. The monitor should be monitoring a patient.
2. The monitor alarm limits should be configured to the patient being monitored.
3. Disconnect the sensor from the monitor.
4.  Press the ALARM SILENCE button. This silences the audible alarms.
5.  Press the ALARM SILENCE button. This disables the alarm messages.



The monitor is now in standby. To return to normal monitoring, connect the sensor to the monitor and the patient.

Adult-Pediatric or Neonatal Settings



The clinician can set the monitor's operating mode to adult-pediatric or neonatal by using the LIMITS softkey. The setting will only remain in the monitor until the monitor is turned off. The factory default power-on setting is for adult-pediatric patients. This default setting can be changed to neonatal by qualified service personnel using the procedures indicated in the service manual.

Refer to Table 11 on page 139, for neonate factory default limit settings. Refer to Table 12 on page 140, for adult factory default limit settings.



WARNING: Each time the pulse oximeter is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Setting Patient Adult-Pediatric/Neonatal Mode

With the monitor in the normal monitoring mode:

- LIMITS
- Press the LIMITS softkey.

ADULT LIMITS			%SP02	
	%SPO2	BPM	<div></div>	---
UPPER	100	170	100	---
LOWER	85	40		---
SAT-S	100		BPM	
SELECT	NEO	ADULT	EXIT	

NEONATE LIMITS			%SP02	
	%SPO2	BPM	<div></div>	---
UPPER	95	190	100	---
LOWER	80	90		---
SAT-S	100		BPM	
SELECT	NEO	ADULT	EXIT	NEO

- The monitor will display the ADULT LIMITS or NEONATE LIMITS screen, depending on the patient setting being used.

- ADULT or
NEO
- Press the NEO or ADULT softkey to select ADULT LIMITS or NEONATE LIMITS as applicable for the patient being monitored.

Alarm Limit Changed Indicator

Alarm limits that have been changed from the institutional or factory default settings are identified by a decimal point (.) after the displayed reading (%SpO₂ or BPM). The changed parameter is also identified by a decimal point on the alarm limits screen.



ADULT LIMITS			%SP02	96.
	%SPO2	BPM		
UPPER	100	170	100	79
LOWER	80.	40	BPM	
SAT-S	100			
SELECT	NEO	ADULT	EXIT	

Setting Alarm Limits

The Alarm Limit display allows the user to adjust the upper and lower saturation and pulse rate limits. It also allows the user to adjust the *SatSeconds* limit.

The Alarm Limit display is accessed by pressing the LIMITS softkey on the Main menu.

The Alarm Limit display includes the alarm limit table and current measured %SpO₂ and pulse rate. The title of the alarm limit table will indicate whether the instrument is in Adult or Neonate monitoring mode. If *SatSeconds* are enabled, the Alarm Limit display also includes the *SatSeconds* indicator. Decimal points after the displayed %SpO₂ or pulse rate indicate that the respective limits have been changed from the power-on defaults.

With the monitor in the normal monitoring mode:

LIMITS



1. Press the LIMITS softkey. Current alarm limits are displayed.

ADULT LIMITS			%SP02	
	%SPO2	BPM		---
UPPER	100	170	100	---
LOWER	85	40		---
SAT-S	100		BPM	
SELECT	NEO	ADULT	EXIT	

or

NEONATE LIMITS			%SP02	
	%SPO2	BPM		---
UPPER	95	190	100	---
LOWER	80	90		---
SAT-S	100		BPM	
SELECT	NEO	ADULT	EXIT	NEO

**ADULT or
NEO**



2. Press the ADULT or NEO softkey to select Adult-Pediatric or Neonatal alarm limits screen.

SELECT



3. Press the SELECT softkey as required to select the parameter to be adjusted.



4. Use the ADJUST UP or ADJUST DOWN buttons to increase or decrease the selected limit parameter.

5. Repeat steps 3, 4, and 5 as necessary to complete the alarm limits setup.

EXIT



6. To accept the changes, let the display time-out or press the EXIT softkey to exit the display and return to normal monitoring.



Note: Limit changes will only be in effect as long as the monitor remains turned on. When the monitor is turned off, the institutional or factory default limits will be restored into the monitor. When the monitor is turned on, the institutional or factory default limits will be in effect. Factory or institutional defaults are selected by qualified service personnel following the procedure in the service manual.

Using the
N-595

Setting SatSeconds Alarm Limit

Refer to *Describing SatSeconds* on page 135, for a description of the *SatSeconds* function.

With the monitor in the normal monitoring mode:

LIMITS



1. Press the LIMITS softkey. Current alarm limits are displayed.

SELECT



2. Press the SELECT softkey twice to select %SpO₂ SAT-S.

ADULT LIMITS				
	%SPO2	BPM	%SP02	
UPPER	100	170		---
LOWER	80.	40	100	---
SAT-S	100		BPM	---
SELECT	NEO	ADULT	EXIT	



3. Use the AJDUST UP or ADJUST DOWN buttons to select the limit. The choices are 10, 25, 50, or 100 seconds or OFF.

EXIT



4. Press the EXIT softkey to save your choice.

Setting Monitor Response Mode

The purpose of the response mode is to set the response time of the OxiMAX algorithm calculation of the SpO₂ (the response mode does not affect the OxiMAX algorithm's calculation of pulse rate). The trending interval (2- or 4-seconds) is updated automatically by the monitor to roughly correspond with the SpO₂ calculation response time.

The response mode programs the OxiMAX algorithm to display monitor trend information at 2-second intervals (Fast Mode) or 4-second intervals (Normal Mode).

The response mode display screen includes the current SpO₂ response mode setting and the current measured %SpO₂ and pulse rate. When in the fast mode, the screen displays the fast mode symbol.

With the monitor in the normal monitoring mode:

- SETUP** 1. Press the SETUP softkey.



- NEXT** 2. Press the NEXT softkey.



- NEXT** 3. Press the NEXT softkey.



- NEXT** 4. Press the NEXT softkey.



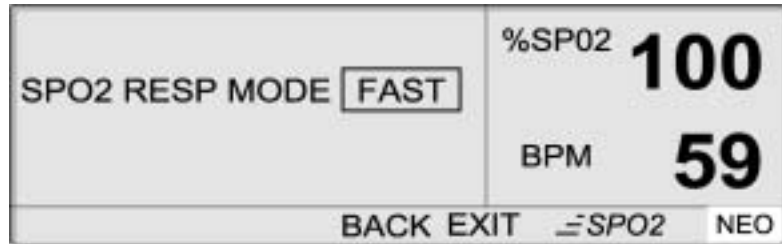
- MODE** 5. Press the MODE softkey.



Note: When the monitor is in the fast response mode the monitor may produce more SpO₂ and pulse rate alarms than the user is



accustomed to seeing, and may be inappropriate in challenging measurement conditions.



6. Use the ADJUST UP or ADJUST DOWN buttons to select the desired response mode.



7. Press the EXIT softkey.

Selecting the Display Language

The N-595 can be programmed to display the information in various languages. The languages available are English, Francais (French), Deutsch (German), Italiano (Italian), Espanol (Spanish), Nederlands (Dutch), Port (Portuguese) and Sverige (Swedish).

With the monitor in the normal monitoring mode:

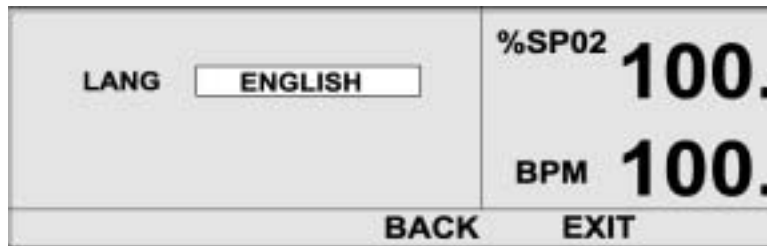


1. Press the SETUP softkey.



2. Press the NEXT softkey.

3. Press the LANG softkey.



4. Use the ADJUST UP or ADJUST DOWN buttons to select the desired language.



5. Press the EXIT softkey.

Note: The selected language will be displayed until the monitor is turned off. The selected language can be set as a default by qualified service personnel following the procedures in the service manual.



OxiMAX Sensor Messages

OxiMAX sensor messages consist of sensor adjust condition messages and sensor adjust messages which, when enabled, are displayed when the monitor is not able to display saturation. When *OxiMAX* sensor messages are displayed, it is an indication that the *OxiMAX* sensor is functioning correctly, but the site to which the *OxiMAX* sensor applies or the application method is not optimal for calculating %SpO₂. Condition messages are followed by action messages. Up to three condition messages may be displayed on the “POOR SIGNAL CONDITION” display in priority order, highest on top. The condition display may be dismissed by using the EXIT softkey. Once exited, the

OxiMAX sensor message screen will not return until a new condition occurs.



POOR SIGNAL CONDITION: -SMALL PULSES -MOTION INTERFERENCE	%SP02	---
	BPM	---
HELP		EXIT

If the HELP softkey is pressed from the Condition message display, the action messages are displayed. Action messages are linked to the sensor type; action messages will be displayed for the type of *OxiMAX* sensor connected to the monitor. Up to five action messages may be displayed. Multiple screens may be required to display all of the messages. When multiple screens are required, navigation between screens can be accomplished through the NEXT, BACK, and EXIT softkeys.

OxiMAX sensor messages may be disabled. Refer to *OXIMAX Sensor Message Setup* on page 127 for selecting the *OxiMAX* Sensor Messages, Enable/Disable function.

SUGGESTED ACTION: -REPOSITION SENSOR -CLEAN SENSOR SITE -NASAL/EAR SENSOR	%SP02	---
	BPM	---
NEXT	BACK	EXIT

***OxiMAX* Sensor Adjust Condition Messages**

- Condition 1 — SENSOR OFF?
- Condition 2 — SMALL PULSES
- Condition 3 — WEAK SIGNAL

- Condition 4 — MOTION INTERFERENCE
- Condition 5 — EXCESS INFRARED LIGHT
- Condition 6 — ELECTRICAL/LIGHT INTERFERENCE
- Condition 7 — HIGH PULSE AMPLITUDE

OxiMax Sensor Adjust Messages

- Message 1 — ALTERNATE SITE?
- Message 2 — COVER SENSOR SITE?
- Message 3 — EAR/FOREHEAD SENSOR?
- Message 4 — NASAL/EAR SENSOR?
- Message 5 — *OxiMax* ADHESIVE SENSOR
- Message 6 — SECURE CABLE
- Message 7 — HEADBAND
- Message 8 — WARM SITE
- Message 9 — BANFAGE ASSEMBLY
- Message 10 — NAIL POLISH
- Message 11 — SENSOR TOO TIGHT?
- Message 12 — REPOSITION SENSOR
- Message 13 — ISOLATE INTERFERENCE SOURCE
- Message 14 — CLEAN SENSOR SITE



Monitor Trend

Monitor Trend Data

The trend displays allow the user to view trend data. Two types of trend data can be viewed:

- Monitor trend data which are stored in the monitor
- Patient event data which are stored in the *OxIMAX* sensor (single-patient-use *OxIMAX* sensors only) and can be used with the sensor event record feature.

Monitor trend data can be viewed anytime patient trend is stored in the monitor. Monitor trend displays are accessed by pressing the TREND softkey on the main menu and selecting the MONITR softkey option. The monitor trend sub-menu allows you to choose which trend data are displayed:

- Saturation and pulse rate (Dual)
- Saturation
- Pulse rate
- Pulse amplitude
- Histogram

The N-595 can graphically display trend data for SpO₂, pulse rate, or both. Trend data is stored at 2- or 4-second intervals. When the TREND softkey is pressed, “READING TRENDS . . .” is displayed at the bottom of the N-595 screen, indicating that the monitor is formatting the trend data to be displayed.

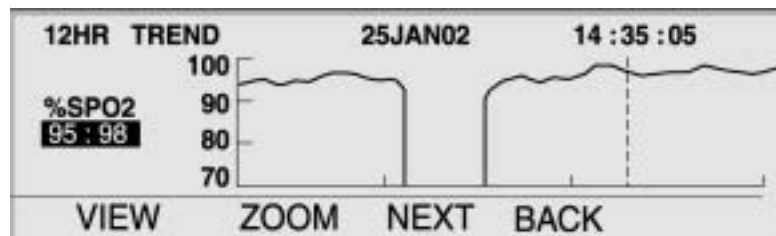




The monitor stores up to 48 hours of 4-second trend data or 24 hours of 2-second trend data. The amount of trend data displayed on the screen is determined by using the ZOOM softkey. The settings available are 20 and 40 seconds, 15 or 30 minutes, and 1, 2, 4, 8, 12, 24, 36, or 48 hours. All trend data are displayed in a graphical format except the 20- and 40-second trend displays, which are shown in tabular format.

The trend display is scrolled, that is, the data displayed can be moved throughout the 48 hours of trend data. Selecting the 1-hour trend display allows you to view one hour of trend information. By using the scrolling feature, any one hour of trend data can be viewed over the 48 hours of trend information. The ADJUST DOWN button scrolls the display to the left and the ADJUST UP button scrolls the display to the right.

When the data are displayed, the most recent readings are on the right side of the graph. The numbers below %SpO₂ indicate the highest and lowest parameter values at the cursor position (vertical dotted line on the display). See Table 4 on page 57.



Trend data is further explained in *Specifications* on page 147.

Trend data information may be retrieved through the N-595 data port or cleared using options available in a display menu.



Caution: Monitor trend data will be lost if the main battery fails or is removed.

Trend Data Operation

Whenever the N-595 is turned on, it stores the monitor %SpO2 and pulse rate readings in memory every 2 or 4 seconds (regardless of whether the N-595 is monitoring a patient or not). The N-595 can store up to 48 hours of 4-second trend data or 24 hours of 2-second trend data. The 48/24 hours of stored trend data are available for downloading to a printer or a portable computer. Up to 50 alarm limit changes can be stored in the trend data. If more than 50 alarm limit changes occur during the 48/24 hours of trend data collection, the additional alarm limit changes will take space reserved for trend data.



Caution: Changing alarm limit settings uses up trend memory space. Change alarm limits only as needed.

Note: Trend memory always contains the most recent 48 hours of data, with newly collected data overwriting the oldest data on a rolling basis. The N-595 continues to record data points as long as the monitor is powered on, with “blank” data points collected if no *OxiMAX* sensor is connected to the monitor or patient. “Blank” data will over-write older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your monitor off when you are not monitoring a patient, and that you download the trend memory before it fills up and over-writes the old data with new data (or “blank” data).

Selecting the Trend Data Display Scale

The trend scale is the amount of trend data displayed on the screen.

With the monitor in the normal monitoring mode:



1. Press the TREND softkey.
2. Press the MONITR softkey.



VIEW



3. Press the VIEW softkey.

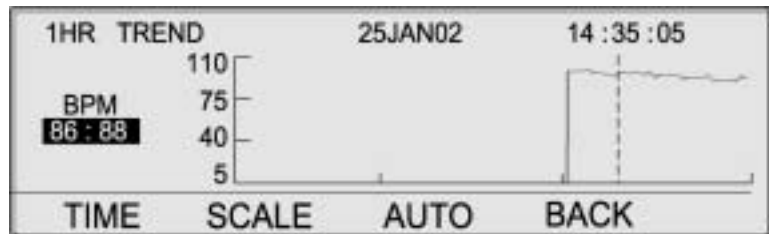


4. Press any of the trend softkeys (DUAL, SPO2, or PULSE). To select HIST (histogram) or AMP (amplitude), press the NEXT softkey and then the HIST or AMP softkeys.

ZOOM



5. Press the ZOOM softkey. The Zoom menu is displayed.



TIME



Pressing the TIME softkey cycles the displayed trend time scale through 48 hours, 36 hours, 12 hours, 8 hours, 4 hours, 2 hours, 1 hours, 30 minutes, 15 minutes, 40 seconds and 20 seconds.

Note: The 20-second and 40-second trend displays are in tabular format. The below display starts out in the normal response mode (left side of the display) and switches to the fast response mode.

40SEC TREND			05JAN02			21:31:48		
TIME	%SPO2	BPM	TIME	%SPO2	BPM	TIME	%SPO2	BPM
21:31:30	96	78	21:31:40	97	78			
21:31:28	--	--	21:31:38	97	79			
21:31:26	97	78	21:31:36	97	80			
21:31:24	--	--	21:31:34	96	78			
21:31:22	97	78	21:31:32	96	78			
TIME			SCALE			AUTO BACK=SPO2		

SCALE



Pressing the SCALE softkey cycles the displayed trend amplitude scale through ± 5 points, ± 10 points, ± 15 points, ± 20 points, ± 25 points, ± 30 points, ± 35 points, ± 40 points and ± 50 points above and below the data point under the cursor. The saturation graphical monitor trend display vertical scale default setting is from 10 to 100 if there is no data under the cursor. The pulse rate graphical monitor

trend display vertical scale is from 5 to 250 if there is no data under the cursor.

- AUTO

Pressing the AUTO softkey presets the amplitude of the graphed trend data. The maximum trend data point is rounded up to the nearest multiple of 10, this value is the top of the graph display. The minimum trend data point is rounded down to the next multiple of 10. Then 10 is subtracted from the rounded down number, this value is the bottom of the trend graph.
- BACK

Pressing the BACK softkey returns the monitor to the Monitor menu.

Reading the Trend Data Display

Table 4 identifies the components of the trend data display.

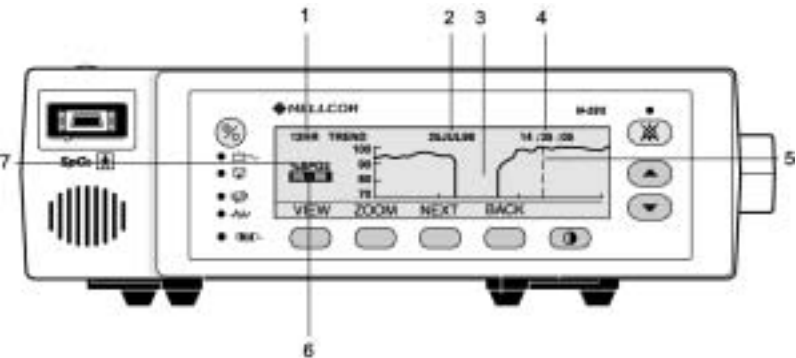


Table 4: Reading Trend Display

Item	Description
1	Amount of trend data displayed on the screen. Settings available are 20 and 40 seconds, 15 and 30 minutes, 1, 2, 4, 8, 12, 24, 36, and 48 hours.
2	Date represented by the cursor (item 5).
3	No trend data recorded during this time.
4	Time represented by the cursor (item 5).

Table 4: Reading Trend Display





Item	Description
5	Cursor - can be moved left or right using the ADJUST UP (right) or ADJUST DOWN (left) buttons.
6	Highest and lowest reading at the cursor position.
7	Trend data that is being displayed (%SPO2, BPM, or PAU [pulse amplitude units]).

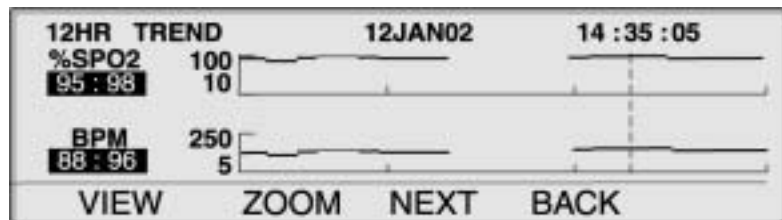
Using the
N-595

Dual Trend Data Display

The dual trend data display displays both oxygen saturation (%SpO2) levels and pulse rate (bpm) trend data.





With the monitor in the normal monitoring mode:

- TREND** 1. Press the TREND softkey.

- MONITR** 2. Press the MONITR softkey.

- VIEW** 3. Press the VIEW softkey.

- DUAL** 4. Press the DUAL softkey. The dual trend (%SpO2 and Pulse Rate) is displayed.


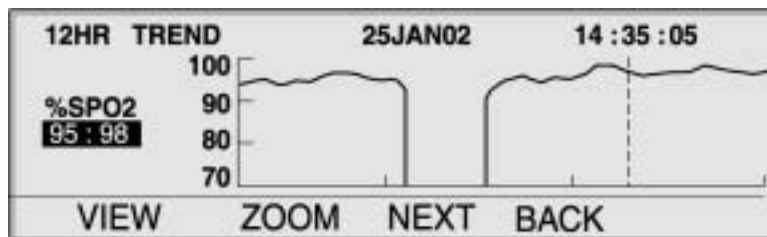


SpO₂ Trend Display

With the monitor in the normal monitoring mode:




- TREND** 1. Press the TREND softkey.

- MONITR** 2. Press the MONITR softkey.

- VIEW** 3. Press the VIEW softkey.

- SPO2** 4. Press the SPO2 softkey. SpO₂ trend data is displayed.


Using the
N-595



Pulse Rate Trend Display

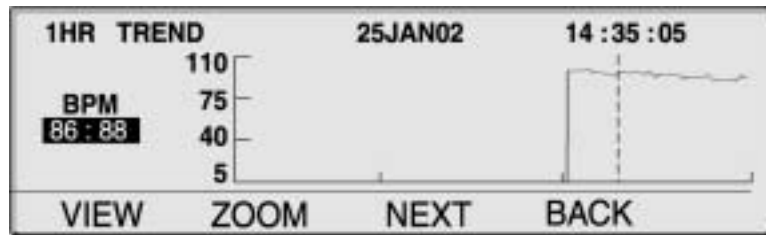
With the monitor in the normal monitoring mode:

- TREND** 1. Press the TREND softkey.

- MONITR** 2. Press the MONITR softkey.

- VIEW** 3. Press the VIEW softkey.


PULSE



4. Press the PULSE softkey. The pulse trend data is displayed.



Using the
N-595

Histogram Trend Data Display

The histogram displays trend data for the percent of oxygen blood saturation (SpO₂) and pulse rate (bpm). The data displayed represents the trend data stored over the period of time indicated on the display. Refer to *Selecting the Trend Data Display Scale* on page 55, to set up the desired trend data scale.

Pulse amplitude cannot be displayed on the histogram display.

With the monitor in the normal monitoring mode:

TREND



1. Press the TREND softkey.

MONTIR



2. Press the MONITR softkey.

VIEW



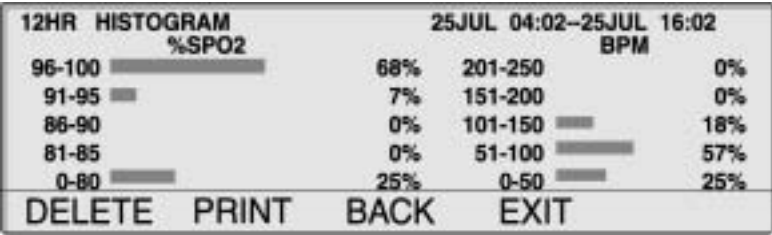
3. Press the VIEW softkey.

NEXT



4. Press the NEXT softkey.

- HIST
5. Press the HIST softkey. The Histogram trend data is displayed.



Pulse Amplitude Trend Data Display

The pulse amplitude trend data display shows the amplitude of the patient's pulse rate over the period of time indicated on the display. Refer to *Selecting the Trend Data Display Scale* on page 55, to setup the desired trend data scale.

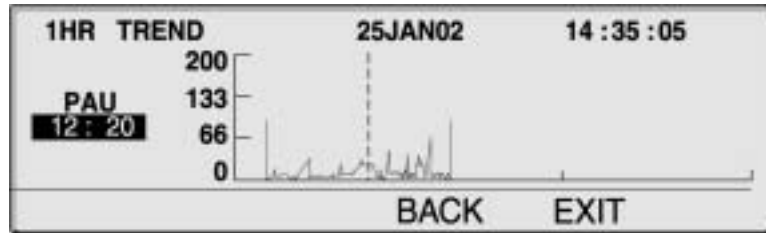
With the monitor in the normal monitoring mode:

- TREND
1. Press the TREND softkey.
- MONITR
2. Press the MONITR softkey.
- VIEW
3. Press the VIEW softkey.
- NEXT
4. Press the NEXT softkey.

AMP



5. Press the AMP softkey. The pulse amplitude units (PAU) trend data is displayed.



The PAU reading (12 : 20) indicates the pulse amplitude units (upper and lower) at the cursor position (dashed line). The cursor is moved right or left using the ADJUST UP (right) and ADJUST DOWN (left) buttons.

Clearing Trend Information

With the monitor in the normal monitoring mode:

TREND



1. Press the TREND softkey.

MONITR



2. Press the MONITR softkey.

NEXT



3. Press the NEXT softkey.

DELETE



4. Press the DELETE softkey.

Note: Press the NO softkey and then the EXIT softkey to leave this function without deleting trend data.

YES



5. Press the YES softkey.

All the trend data is cleared and the monitor sounds three beeps.



OXIMAX Sensor Event Record



WARNING: The sensor extrapolates from the date and time provided by the N-595 when recording the sensor event record to the sensor. The accuracy of the date/time is the responsibility of the N-595. It is recommended that the N-595 user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

Using the
N-595

The adhesive *OXIMAX* sensors are capable of storing patient event data. A sensor event record allows alarm event history to travel with the patient on the sensor's memory chip for quick assessment at every point of care where *OXIMAX* monitors are used.

Patient (event) data is stored on the memory chip of adhesive *OXIMAX* sensors (single-patient-use *OXIMAX* sensors only). The event data is stored (recorded) with the limit/threshold settings that were active at the time of the event on the recording monitor. These events can be viewed on the next *OXIMAX* sensor monitor when the patient moves to a new point of care.

An event occurs when the %SpO₂ value exceeds either the upper or lower alarm limit for at least 15 seconds. The first *OXIMAX* sensor event record event will be stored in the *OXIMAX* sensor after the *OXIMAX* sensor has been attached to a patient for five minutes and every five minutes thereafter. The maximum number of events that can be stored in an *OXIMAX* sensor is 100.



Event records can only be viewed after an *OxiMAX* sensor containing patient data (event records) has been connected to an *OxiMAX* monitor. Event records are designed to view patient events from prior areas of care or transport (history) while monitor trend should be used to view data or events from a patient currently being monitored. The monitor's SENSOR EVENT RECORD indicator will light when an *OxiMAX* sensor containing event data is connected to the *OxiMAX* monitor.

Patient event data is accessed by pressing the TREND softkey on the main menu and selecting the SENSOR softkey option. Sensor event record can be viewed in graphical form (GRAPH) or in a summary table (TABLE).

Note: Once the *OxiMAX* sensor event record type is set up in the *OxiMAX* sensor and event data is stored in the *OxiMAX* sensor, the *OxiMAX* sensor event record type cannot be reset. The monitor's type set up can be changed at any time.

Recording and viewing of *OxiMAX* sensor event record is only available on *OxiMAX* comparable monitors. The *OxiMAX* sensors may function on older technology monitors but the *OxiMAX* sensor event record feature is not available.

Refer to the N-595 service manual for the procedure to disable the storage of sensor event record on an *OxiMAX* sensor.

Setting In-Sensor Data Type

The In-Sensor Data Type display allows the user to set the type of trend data to be recorded in an *OxiMAX* sensor. *OxiMAX* sensors can be set to record either SpO₂ or SpO₂+BPM.

Note: The *OxiMAX* sensor data type can only be set when an *OxiMAX* sensor is not connected to the monitor.

With the monitor turned on and no cable attached to the SpO₂ *OxiMAX* sensor port:

- SETUP** 1. Press the SETUP softkey.



- SENSOR** 2. Press the SENSOR softkey.



- DATA** 3. Press the DATA softkey.



Note: *OXIMAX* sensor data type settings are displayed on the monitor as shown in the figure below (in-sensor data type). If no sensor is connected, both sensor types and the full set of options for each are displayed. If a sensor is connected, only the sensor data type for that sensor is displayed.

IN-SENSOR DATA TYPE		%SP02
SENSOR-R	<input type="text" value="SPO2"/>	---
SENSOR-RW	SPO2+BMP	BPM ---
SELECT	BACK	EXIT

Note: The SENSOR-R feature supports all the current *OXIMAX* sensors. The SENSOR-RW feature is only applicable to *OXIMAX* sensors with a read/write chip installed.

- SELECT** 4. Use the SELECT softkey to toggle between SENSOR-R and SENSOR-RW.





5. Use the ADJUST UP or ADJUST DOWN button to select the *OxiMAX* sensor data type. SENSOR-R and SENSOR-RW selections are:

- SpO2
- SpO2+BPM
- DEFAULT



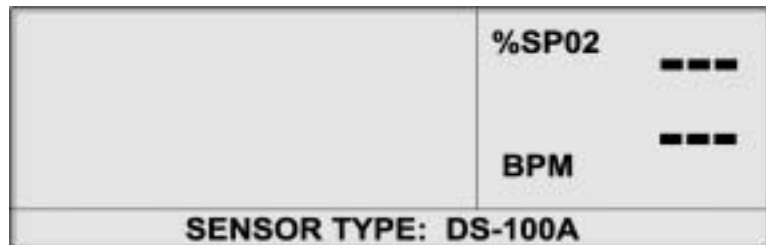
EXIT



6. Press the EXIT softkey to set the *OxiMAX* sensor type.

***OxiMAX* Sensor Type**

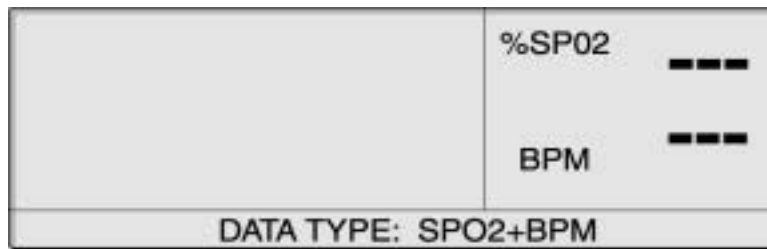
When an *OxiMAX* sensor is connected to the monitor, a “SENSOR TYPE: ...” message is displayed for 4 to 6 seconds at the bottom of the display. The message identifies the type (model) of *OxiMAX* sensor connected to the monitor. Type is used in the determination of action messages in the *OxiMAX* sensor message(s) function. This display is the first message displayed when an *OxiMAX* sensor is connected to the monitor.



***OxiMAX* Sensor Data Type**

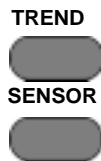
When an *OxiMAX* sensor with no previously recorded patient data is connected to the *OxiMAX* monitor, a “DATA TYPE: . . .” message is displayed briefly at the bottom of the display, this message is

displayed after the *OxiMAX* sensor type message. The message identifies the monitor's current data type setting that will be used to write data to the *OxiMAX* sensor. The data type setting options are EVENT/SPO₂ and EVENT/SPO₂+BPM.



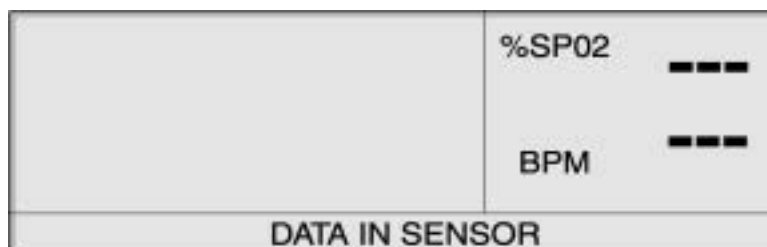
The user can change the setting by referring to *Setting In-Sensor Data Type* on page 66. The *OxiMAX* sensor event record type must be set prior to connecting the *OxiMAX* sensor to the monitor.

OxiMAX Sensor Event Record Data Available



When an *OxiMAX* sensor containing data (single-patient-use *OxiMAX* sensors only) is connected to the monitor, the Sensor Event Record indicator on the monitor front panel blinks at a medium priority flash rate to indicate that the *OxiMAX* sensor attached to the monitor contains patient event data. The LED blinks for approximately 60 seconds or until the *OxiMAX* sensor is disconnected or until the sensor trend data is displayed by pressing TREND, then SENSOR.

A corresponding "DATA IN SENSOR" message is also displayed at the bottom of the display. After 4 to 6 seconds, if all the data has been read from the *OxiMAX* sensor, the message is replaced with the main menu.



If data is still being read from the *OxiMAX* sensor, after 4 to 6 seconds, the DATA IN SENSOR message is replaced with a READING TRENDS message with an ABORT option.



Selecting the ABORT softkey stops the recording of additional data in the *OxiMAX* sensor and accessing or viewing the data that is in the *OxiMAX* sensor.

Sensor event record can be viewed by accessing the TREND/SENSOR menu.

The SENSOR EVENT RECORD LED comes on steady when *OxiMAX* sensor memory is full and stays on until the *OxiMAX* sensor is disconnected.

***OxiMAX* Sensor Event Record Not Available**

If the user selects the TREND/SENSOR option when a connected *OxiMAX* sensor (single-patient-use *OxiMAX* sensors only) does not contain data, because no events were recorded to the *OxiMAX* sensor memory chip in the prior monitoring situation, a “NO DATA” message is displayed on the default trend or event graph.

A sample event display in which no data are available is shown below. The message will be cleared when the graph or summary is exited.



***OXI*MAX Sensor Event Record Graphical Data**

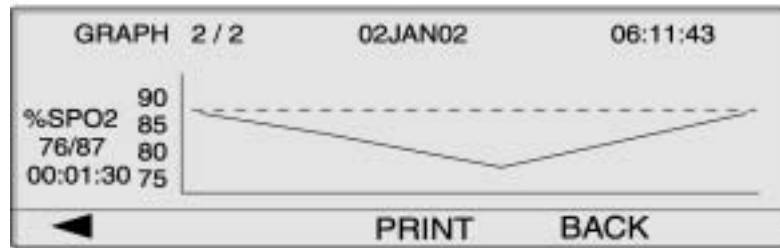
Graphical representations of patient event history is only available on single-patient-use *OXI*MAX sensors. Graphed data points are the minimum or maximum %SpO₂ value for each 30-second interval throughout the duration of an event (%SpO₂ continuously below alarm threshold for at least 15 seconds) and continuing every 30 seconds until the actual %SpO₂ value equals or exceeds the alarm threshold.

The duration of an event is determined by the number of data points in the event. Each data point is stored at 30-second intervals.

Events end for one of four reasons:

- The %SpO₂ returns to or above the alarm limit
- Loss of pulse
- The *OXI*MAX sensor is disconnected

- The *OxiMAX* sensor is off the patient



The graph title shows the data type (EVENT GRAPH) in the upper left corner. The number of the displayed event and the total number of events recorded in the *OxiMAX* sensor are shown to the right of the title (example, 2/2). The date and time of the displayed event are shown in the upper center and upper right corner.

The type of data displayed in the graph is indicated to the left of the vertical axis (%SpO₂). Below this is the range of values (min/max) during the event. The duration of the event is shown below the range value. The vertical axis of the graph is labeled to show the magnitude scale of the graphed data. The horizontal axis is not labeled but automatically scales to accommodate the number of 30-second intervals during the event. The alarm threshold (lower than %SpO₂ alarm limit) is represented by a horizontal dotted line across the graph. The first data point is always the alarm threshold.

Events are displayed one at a time, one per graph. Graphs are displayed in chronological sequence with the most recent event shown first when accessing the graphical *OxiMAX* sensor event display. The user can move between events by using the two left-most softkeys which are labeled with left- and right-facing arrow icons, respectively. At the beginning of an event sequence, event 1 of 2 events, the left-arrow soft key is blank; at the end of a sequence, event 2 of 2 events, the right-arrow soft key is blank.

The ADJUST UP and ADJUST DOWN buttons on the monitor panel can also be used to move through events.

The PRINT softkey allows the user to print the displayed event graph. The BACK softkey takes the user back to the previous TREND/SENSOR sub-menu level.

Viewing and Printing OxiMAX Sensor Event History Data

With the monitor in the normal monitoring mode. You must connect a printer, capable of printing graphs, to the monitor data port connector to print *OxiMAX* sensor event history data.

The monitor protocol must be set to GRAPH to print the in-sensor event history data. Refer to *Printing Monitor Trend Information* on page 79. To view and print in-sensor event history data:

1. Connect an *OxiMAX* sensor containing patient data to the monitor.

TREND



2. Press the TREND softkey.

SENSOR

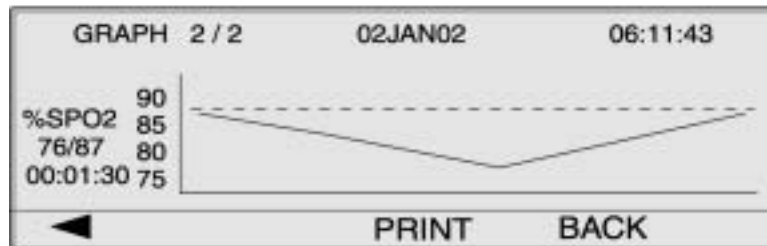


3. Press the SENSOR softkey.

GRAPH



4. Press the GRAPH softkey.



Note: Use the left and right arrow softkeys to scroll through the pages of the event graph.

PRINT



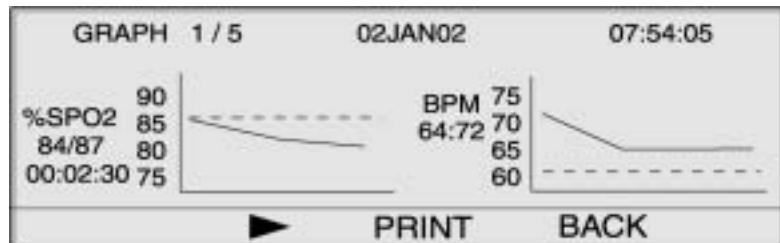
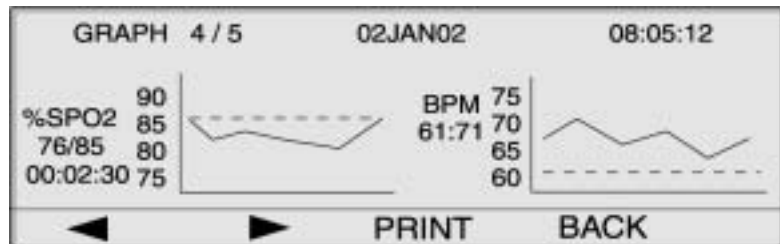
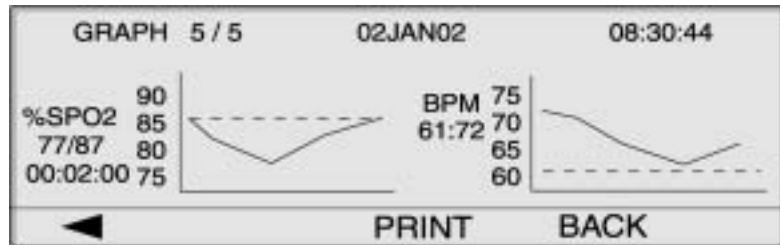
5. Press the PRINT softkey to print the displayed screen.

EXIT



6. Press the EXIT softkey.

A sequence of %SpO₂ + BPM (saturation plus pulse rate) “dual-view” event graphs are shown below. The dual-view graph is the same as a single graphical event history graph except the graphs are compressed horizontally to allow both %SpO₂ and pulse rate graphs to be shown for the same event.



OXIMAX Sensor Tabular Event Data

The *OXIMAX* sensor tabular event data is a listing of all events recorded on the *OXIMAX* sensor's memory chip.

SUMMARY					
#	DATE	START	DUR	%SPO2	BPM
4	02JAN	11:07	00:10:30	76/83	60/64
3	02JAN	10:30	00:06:30	79/84	57/64
2	02JAN	09:57	00:02:00	82/84	59/63
1	02JAN	09:46	00:05:30	75/82	56/61
			▶	PRINT	BACK

SUMMARY					
#	DATE	START	DUR	%SPO2	BPM
100	02JAN	13:55	00:03:00	75/80	63/70
99	02JAN	11:07	00:10:30	76/83	60/64
98	02JAN	10:30	00:06:30	79/84	57/64
97	02JAN	00:02	00:02:00	82/84	59/63
▲			▼	PRINT	BACK

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The table title shows in the upper left corner. Below the table title is a six-column table with left-to-right column headings of event number (#), date (DATE), event start time (START), event duration (DUR), %SPO2 minimum and maximum values during the event (%SPO2), and pulse rate minimum and maximum values during the event (BPM).

Event data are listed in chronological order with the most recent event shown first, at the top of the list, when the tabular Event Summary display is first accessed. Four events can be displayed simultaneously; the table must be scrolled to view additional events. The user can move to the next screen view of the table, the next three events (the previously displayed bottom or top event is retained as the fourth event for context when a table is scrolled), using the two left-most softkeys which are labeled with left- and right-facing arrow icons, respectively. At the beginning of an event sequence, Event 1 of 5 events, the left-arrow soft key is blank; at the end of a sequence,

Event 5 of 5 events, the right-arrow soft key is blank, indicating you have reached the beginning or end of the table.

The ADJUST UP and ADJUST DOWN buttons on the monitor panel can be used to move through the Event Summary table line by line.

The PRINT softkey allows the user to print the displayed event graph.

The BACK softkey takes the user back to the previous TREND/SENSOR sub-menu level.

Using the
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Viewing and Printing In-Sensor Tabular Event History Data

The monitor should be in the normal monitoring mode.

To view and print in-sensor tabular event history data:

- TREND** 1. Press the TREND softkey.



- SENSOR** 2. Press the SENSOR softkey.



- TABLE** 3. Press the TABLE softkey.



SUMMARY					
#	DATE	START	DUR	%SPO2	BPM
100	02JAN	13:55	00:03:00	75/80	63/70
99	02JAN	11:07	00:10:30	76/83	60/64
98	02JAN	10:30	00:06:30	79/84	57/64
97	02JAN	00:02	00:02:00	82/84	59/63
▲		▼		PRINT	BACK

- PRINT** 4. Press the PRINT softkey to print the data.



BACK



5. Press the BACK softkey.

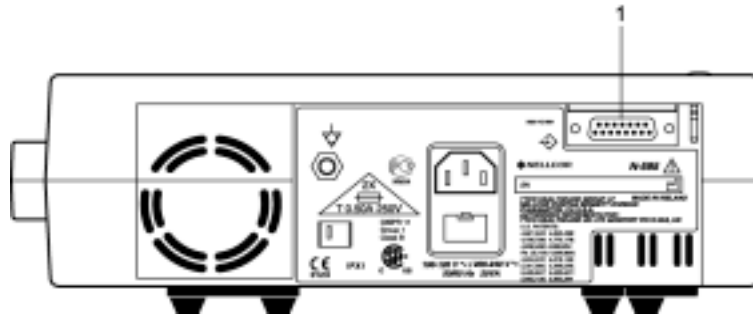


Printing

Printing Monitor Trend Information

Trend information (monitor and in-sensor event history) may be sent to a personal computer or to a serial printer.

Note: The protocol settings must be set to ASCII MODE for printing text data or GRAPH MODE for printing graphical data.



1. Data Port Connector

With the monitor in the normal monitoring mode:

1. Connect the serial printer to the monitor's DATA PORT connector (1), using Nellcor printer cable part number 036341.
2. Turn on the printer.

SETUP



3. Press the SETUP softkey.

NEXT



4. Press the NEXT softkey.



NEXT



5. Press the NEXT softkey.

COMM



6. Press the COMM softkey.

SERIAL PORT SETUP		%SP02	100.
BAUD	9600	BPM	100.
PROTOCOL	ASCII		
SELECT	BACK	EXIT	



7. Set the BAUD rate to the appropriate number using the ADJUST UP button.

SELECT



8. Press the SELECT softkey to select PROTOCOL.



9. Set the PROTOCOL to ASCII for text printing or GRAPH for graph printing using the ADJUST UP button.

EXIT



10. Press the EXIT softkey.

TREND



11. Press the TREND softkey.

MONITR



12. Press the MONITR softkey for monitor trend printing or press the SENSOR softkey for in-sensor event history data printing.

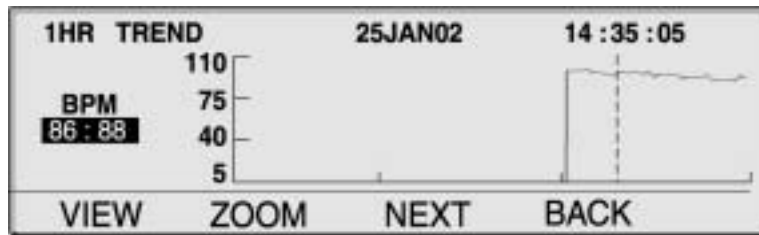
SENSOR



NEXT



13. Press the NEXT softkey.



PRINT

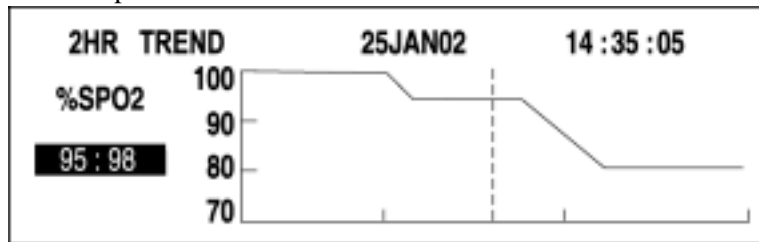


14. Press the PRINT softkey.

ASCII printout:

N-595	VERSION 1.0.0.0	TREND	SpO2 Limit: 85-100% PR Limit: 40-170BPM		
ADULT		OSAT-S	SPO2 RESP MODE: NORMAL		
TIME		%SpO2	BPM	PA	STATUS
12-JAN-02	14:00:05	100	120	150	
12-JAN-02	14:00:09	100	121	154	
12-JAN-02	14:00:13	100	120	150	
Output Complete					

GRAPH printout:



Using the
N-595

Monitor Trend Data in ASCII Mode

Refer to *Printing Monitor Trend Information* on page 79 for the procedure to print trend information.



The format of data displayed when a trend printout is shown in Figure 3. “TREND” is displayed in the top row.

Readings are displayed in 2- or 4-second intervals depending on the response mode selected. The values on each row are an average of the response mode selected period.

At the end of the printout an “Output Complete” line indicates that the transmission was successful. If the “Output Complete” line is not present, a corruption of the data may have been detected and the data should be ignored.

N-595	VERSION 1.0.0.0	TREND	SpO2 Limit: 85-100% PR Limit: 40-170BPM		
	ADULT	OSAT-S	SPO2 RESP MODE: NORMAL		
TIME		%SpO2	BPM	PA	STATUS
12-JAN-02 14:00:05		100	120	150	
12-JAN-02 14:00:09		100	121	154	
12-JAN-02 14:00:13		100	120	150	
Output Complete					

Figure 3: ASCII Mode Printout

Once a trend printout has begun, it cannot be aborted without turning off the N-595 or the printer.

Trend Data in Graph Mode

Refer to *Printing Monitor Trend Information* on page 79 for the procedure to print trend information. See Figure 4 on page 83.

The graph mode disables all printout functions except trend data. Graph mode trend printouts are formatted for a Seiko DPU-414 and Okidata 320 serial printer.

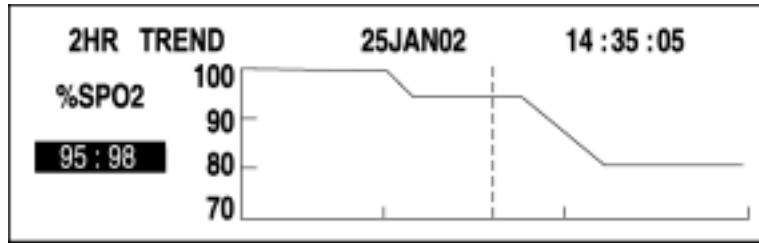


Figure 4: Graph Mode Printout



Real-Time Display/Printout Format

Real-time data is continuously sent to the data port on the back of the N-595. Patient data can be obtained through the data port by connecting the monitor data port to a PC or serial printer. When a real-time printout or display is being transmitted to a printer or PC, a new line of data is displayed every 2 seconds. Column headings are displayed or printed after every 25 lines, or if one of the values in the column heading changes. Readings are displayed at 4-second intervals if the SpO₂ response mode is set to normal and at 2-second intervals when the SpO₂ response mode is set to fast.

Data cannot be obtained if the N-595 is operating on battery power.

Note: If the data output stops transmitting, turn the power off and back on again or, if the monitor is connected to a PC, send an XON (Ctrl-q) command to reset the monitor.

An example of a real-time output is shown in Figure 5 on page 84.



N-595 VERSION 1.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM							
ADULT		OSAT-S	SPO2 RESP MODE: NORMAL				
TIME		%SpO2	BPM	PA	Status		
12-JAN-02 14:00:06		100	120	50			
12-JAN-02 14:00:07		100	124	50			
12-JAN-02 14:00:09		100	190*	52	PH		
12-JAN-02 14:00:11		100	190*	50	PH		
12-JAN-02 14:00:13		100	190*	51	PH		
12-JAN-02 14:00:15		100	190*	50	PH		
12-JAN-02 14:00:17		100	190*	50	PH		
12-JAN-02 14:00:19		100	190*	51	PH		
12-JAN-02 14:00:21		100	190*	53	PH	LB	
12-JAN-02 14:00:23		100	190*	50	PH	LB	
12-JAN-02 14:00:25		100	090*	50	PH	LB	
12-JAN-02 14:00:27		---	---	---	SD	LB	
12-JAN-02 14:00:29		---	---	---	SD	LB	
12-JAN-02 14:00:31		---	---	---	SD		
12-JAN-02 14:00:33		---	---	---	SD		
12-JAN-02 14:00:35		---	---	---	SD		
12-JAN-02 14:00:37		---	---	---	SD		
12-JAN-02 14:00:39		---	---	---	SD		
12-JAN-02 14:00:41		---	---	---	SD		
12-JAN-02 14:00:43		---	---	---	SD		
12-JAN-02 14:00:45		---	---	---	SD		
12-JAN-02 14:00:47		---	---	---	SD		
12-JAN-02 14:00:49		---	---	---	SD		
N-595 VERSION 1.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM							
ADULT		OSAT-S	SPO2 RESP MODE: NORMAL				
TIME		%SpO2	BPM	PA	Status		
12-JAN-02 14:00:51		---	---	---	SD		
N-595 VERSION 1.0.0.0 CRC: XXXX SpO2 Limit: 80-100% PR Limit: 40-170BPM							
ADULT		OSAT-S	SPO2 RESP MODE: NORMAL				
TIME		%SpO2	BPM	PA	Status		
12-JAN-02 14:00:53		79*	59	50	SL	PL	LB
12-JAN-02 14:00:55		79*	59	50	PS	SL	PL
						PL	LB

Figure 5: Real-Time Printout

Column Headings

Every 25th line of the data consists of a column heading.

N-595	VERSION 1.0.0.0	CRC: XXXX	SpO2 Limit: 85-100%	PR Limit: 40-170BPM
	ADULT	OSAT-S	SPO2 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

A column heading is also output whenever a value of the column heading is changed. There are three column-heading lines shown in the printout. Using the top row as the starting point there are 25 lines before the second row of column headings is printed. The third row of column headings was displayed because the operator changed the SpO2 lower alarm limit from 85 percent to 80 percent.



Data Source

N-595	VERSION 1.0.0.0	CRC: XXXX	SpO2 Limit: 85-100%	PR Limit: 40-170BPM
	ADULT	OSAT-S	SPO2 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

Data in the highlighted box above represents the model number of the monitor, in this case the N-595.

Software Version

N-595	VERSION 1.0.0.0	CRC: XXXX	SpO2 Limit: 85-100%	PR Limit: 40-170BPM
	ADULT	OSAT-S	SPO2 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

The next data field tells the user the software level (Version 1.0.0.0) and a software verification number (CRC: XXXX). Neither of these numbers should change during normal operation. The numbers may change if the monitor is serviced and receives a software upgrade.

Alarm Limits



N-595	VERSION 1.0.0.0	CRC: XXXX	SpO2 Limit: 85-100%	PR Limit: 40-170BPM
	ADULT	OSAT-S	SP02 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

The last data field in the top line indicates the upper and the lower alarm limits for %SpO2 and for the pulse rate (PR). In the example above the lower alarm limit for SpO2 is 85% and the upper alarm limit is 100%. Pulse Rate alarm limits are 40 and 170 bpm. The *SatSeconds* alarm limit (OSAT-S) displays the *SatSeconds* alarm setting. In this example *SatSeconds* is set to off.

Monitor Mode

N-595	VERSION 1.0.0.0	CRC: XXXX	SpO2 Limit: 85-100%	PR Limit: 40-170BPM
	ADULT	OSAT-S	SP02 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

The monitor mode (ADULT or NEONATE) is identified on the printout.

Response Mode

N-595	VERSION 1.0.0.0	CRC: XXXX	SpO2 Limit: 85-100%	PR Limit: 40-170BPM
	ADULT	OSAT-S	SP02 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

The response mode (NORMAL or FAST) is identified on the printout.

Data Column Headings

N-595 VERSION 1.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM					
ADULT		OSAT-S	SPO2 RESP MODE: NORMAL		
TIME	%SpO2	BPM	PA	Status	

Actual column headings are in the second row of the column heading line. Patient data presented in the chart, from left to right, is the:

- time the patient data were obtained
- current %SpO2 value
- current Pulse Rate (BPM)
- current Pulse Amplitude (PA)
- operating status of the N-595.



Time

TIME	%SpO2	BPM	PA	Status
12-JAN-02 14:00:05	100	190*	50	

The Time column represents the N-595 real-time clock.

Patient Data

N-595 VERSION 1.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM					
ADULT		OSAT-S	SPO2 RESP MODE: NORMAL		
TIME	%SpO2	BPM	PA	Status	
12-JAN-02 14:00:05	100	190*	50		

Patient data are highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this

example the %SpO₂ is 100, and the pulse rate is 190 beats per minute. The “*” next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available, three dashes (- - -) will be displayed.

PA represents pulse amplitude. The number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information as an indication of a change in pulse volume, relative pulse strength, or circulation.



Operating Status

N-595 VERSION 1.0.0.0 CRC: XXXX SpO ₂ Limit: 85-100% PR Limit: 40-170BPM					
ADULT		OSAT-S	SPO ₂ RESP MODE: NORMAL		
TIME		%SpO ₂	BPM	PA	Status
12-JAN-02 14:00:05		100	165	50	PH

The Status column indicates alarm conditions and operating status of the N-595. In this example, the PH means that the pulse rate upper alarm limit (Pulse High) has been exceeded. A complete listing of the status codes is listed below. As many as four codes can be displayed at one time in the Status column.

Code	Meaning
AO	Alarm Off
AS	Alarm Silence
LB	Low Battery
LM	Loss of Pulse w/ Motion
LP	Loss of Pulse
MO	Patient Motion
PH	Pulse Rate Upper Limit Alarm
PL	Pulse Rate Lower Limit Alarm
PS	Pulse Search

Code	Meaning
SH	Saturation Upper Limit Alarm
SL	Saturation Lower Limit Alarm
SD	Sensor Disconnect
SO	Sensor Off

Note: An *OxiMAX* sensor disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the display or printout.



Using the Data Port

Overview

Patient data can be output through the data port on the back of the N-595 by connecting it to an attached PC or serial printer.

When connecting the N-595 to a printer or PC, verify proper operation before clinical use. Both the N-595 and the printer or PC must be connected to a grounded AC outlet. The N-595 protocol setting must be ASCII.

Any printer or PC connected to the monitor's data port must be certified according to IEC Standard 950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2.



Connecting to the Data Port

The N-595 data port may be connected to a serial printer or PC by using a cable terminated with an AMP connector (AMP part number 747538-1), ferrule (AMP part number 1-747579-2), and compatible pins (AMP part number 66570-2). The cable should be no more than 25 feet (7.6 meters) in length. The external ITE (Information Technology Equipment) device must be certified to UL-1950 or IEC-60950.

The cable used must have a braided shield providing 100% coverage, such as a Belden cable (Belden part number 9609) or equivalent. The shield must have a 360-degree connection to the metal shell on the

N-595's DB-15 connector and to the connector on the PC or serial printer. Do not create sharp bends in the cable, as this may tear or break the shielding.

No hardware flow control is used. However, in the ASCII mode XON/XOFF flow control is supported.

Using the
N-595

Data Port Pinouts

The pinouts for the data port are listed in Table 5 on page 92.

Table 5: Data Port Pinouts

Pin	Signal Name
1	RXD+ (RS-422 [+] input)
2	RXD_232 (RS-232 input)
3	TXD_ (RS-232 output)
4	TXD+ (RS-422 [+] output)
5	Signal Ground (isolated from Earth Ground)
6	AN_SpO2 (analog saturation output)
7	NC_NO (relay closure nurse call, normally open)
8	NC_NC (relay closure nurse call, normally closed)
9	RxD- (RS_422 [-] input)
10	Signal Ground (isolated from Earth Ground)
11	Nurse Call (RS-232-level-output)
12	TxD- (RS-422 [-] output)
13	AN_PULSE (analog pulse rate output)
14	AN_PLETH (analog pleth waveform output)
15	NC_COM (relay closure nurse call, common lead)

TxD represents the Transmit Data line, and RxD is the Receive Data line.

The pin layouts (as viewed from the rear panel of the N-595) are illustrated in Figure 6 on page 93. The conductive shell is connected to earth ground when connected to a PC or printer.



Figure 6: Data Port Pin Layout

Pins 2, 3, and 5 provide data in RS-232 format.

Pins 1, 4, 9, and 12 provide data in RS-422 format. TxD+ and TxD- are the differential transmit data pair. RxD+ and RxD- are the differential receive pair.

Data Port Setup

Use the Data Port Setup display to set the baud rate and the protocol of the data port on the N-595.

The Data Port Setup display is accessed by pressing the COMM softkey on the Setup menu.

With the monitor in the normal monitoring mode:

1. Press the SETUP softkey.
2. Press the NEXT softkey.
3. Press the NEXT softkey.



COMM



4. Press the COMM softkey.

SERIAL PORT SETUP		%SP02	100.
BAUD	9600	BPM	100.
PROTOCOL	ASCII		
SELECT	BACK	EXIT	



5. Press the ADJUST UP or ADJUST DOWN buttons to select the desired baud rate.

SELECT



6. Press the SELECT softkey to select protocol.



7. Press the ADJUST UP or ADJUST DOWN buttons to select the desired protocol. The available protocols are:

- ASCII
- CLINICAL
- GRAPH
- OXINET
- AGILENT (HP Agilent)
- SPACELBS (Spacelabs)
- MARQ (GE Marquette)
- DATEX (Datex-Ohmeda)

EXIT



8. Press the EXIT softkey.

Using the Nurse Call Interface



WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the pulse oximeter, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.



WARNING: The nurse call feature is not functional whenever the pulse oximeter alarms are silenced.

The nurse call feature of the N-595 monitor is operational when the monitor is powered by AC power or battery power. The nurse call feature of the N-595 works in conjunction with the nurse call system of your institution when the monitor sounds an audible alarm. It is accessed through the data port pins 7, 8, 10, 11, or 15 as indicated in Table 5 on page 92.

The N-595 provides two different types of nurse call interfaces: an RS-232 level and relay closure. The RS-232 level nurse call function operates when the monitor is connected to AC power or on battery. The relay-based nurse call function is available when the monitor is operating either on AC power or on battery power.

The remote location is signaled anytime there is an audible alarm. If the audible alarm has been turned off or silenced, the nurse call function is also turned off.

Pin 11 on the data port is the RS-232 level nurse call signal and pin 5 or 10 is ground (see Table 5 on page 92). When there is no alarm condition, the voltage between pins 10 and 11 is -5 to -12 VDC. Whenever the monitor is in an alarm condition, the output between pins 10 and 11 is +5 to +12 VDC.

Pins 7 and 15 provide a relay that closes when an alarm is sounding on the monitor. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays.





The nurse call function needs to be tested after it has been set up in your facility. The nurse call feature should be tested whenever setting up the N-595 pulse oximeter in a location that uses nurse call. If an attached *OxiMAX* sensor is not connected to a patient, the monitor display reads zeros and the monitor remains in the Pulse Search Mode for 5 seconds, then the monitor displays “---” (3 dashes) in the %SpO₂ and pulse rate display. One way to test the nurse call function is to create an alarm condition (for example, sensor disconnect) and verify that your facility's nurse call system is activated.

Setting Nurse Call RS-232 Polarity

The nurse call polarity can be set to a positive signal (NORM +) on a monitor alarm condition or a negative signal (NORM -) on a monitor alarm condition.

With the monitor in the normal monitoring mode:

1. Press the SETUP softkey.



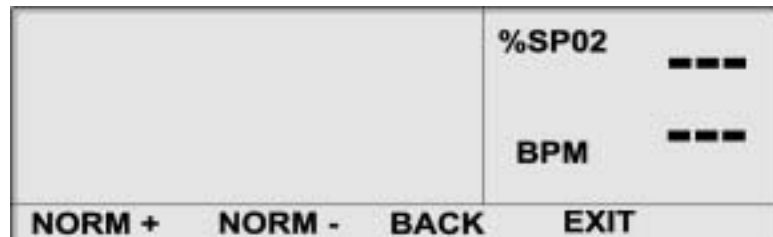
2. Press the NEXT softkey.



3. Press the NEXT softkey.




4. Press the NCALL softkey.



5. Press the NORM + softkey.

NORM +



or

6. Press the NORM - softkey.



7. Press the EXIT softkey.



Setting Nurse Call Relays Normally Open/Closed

Data port pins 7 and 15 provide a relay that closes when an alarm is sounding on the monitor. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays. The relay operates whether the monitor is operating on AC power or battery.

Calculating the Analog Voltage Output

The N-595 data port provides analog voltage outputs between pins 6, 13, 14, and ground (pin 10), which can be used to calibrate instruments such as a chart recorder. The voltage represents a specific measured parameter's current value. The voltage differential varies proportionally from 0 to 1 volt as the pin's parameter varies over its full range of values, as indicated in Table 6 on page 97.






Table 6: Analog Pinouts

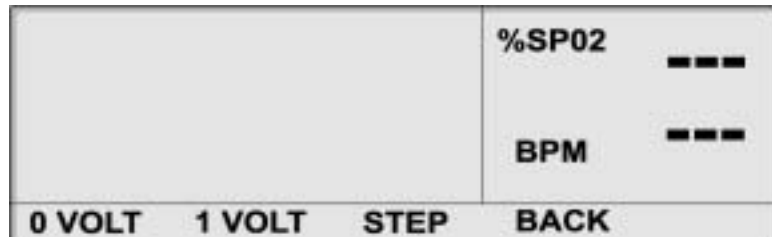
Pin	Parameter	Parameter Range
6	%SpO2	0 - 100%
13	Pulse Rate	0 - 250 bpm
14	Pleth Waveform	0 - 255

For example, as the current value of %SpO₂ varies from 0 to 100%, the voltage from pin 6 to ground (pin 10) varies from 0 to 1 volt. A voltage of 0.94 volts indicates a current %SpO₂ value of 94.

The analog function can be accessed from the main menu:



- | | |
|---|------------------------------|
| SETUP | 1. Press the SETUP softkey. |
|  | |
| NEXT | 2. Press the NEXT softkey. |
|  | |
| NEXT | 3. Press the NEXT softkey. |
|  | |
| NEXT | 4. Press the NEXT softkey. |
|  | |
| ANALOG | 5. Press the ANALOG softkey. |
|  | |



Selecting the 0 VOLT or 1 VOLT softkey causes that voltage to appear at pins 6, 13, or 14 as referenced to ground pins 5 and 10.

Selecting the STEP softkey causes the voltage to increase from 0 to 1 volt at 1/10th-volt increments, with each step lasting at least 1 second.

Qualified service personnel, using the procedure described in the N-595 service manual, can perform calibration of the attached device.

OxIMAX Sensors and Accessories



WARNING: The sensor extrapolates from the date and time provided by the N-595 when recording the sensor event record to the sensor. The accuracy of the date/time is the responsibility of the N-595. It is recommended that the N-595 user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

OxIMAX Sensor Event Record Data

The N-595 records a patient's *OxIMAX* sensor %SpO₂ event history from the *OxIMAX* sensor's memory chip, allowing a patient's event history to travel with the patient as the patient moves throughout the hospital. This allows caregivers to assess whether the patient had a bad event during transport or in the previous area of care. This feature is only available with adhesive single-patient-use *OxIMAX* sensors. Single-patient-use *OxIMAX* sensors are intended for single-patient use only; recorded %SpO₂ event history data does not distinguish between events that have been collected from multiple patients.

Sensors and
Accessories

Selecting an OxIMAX Sensor



WARNING: Before use, carefully read the *OxIMAX* sensor directions for use, including all warnings, cautions, and instructions.



WARNING: Do not use a damaged *OxiMAX* sensor or pulse oximetry cable. Do not use an *OxiMAX* sensor with exposed optical components.



WARNING: Use only Nellcor-approved *OxiMAX* sensors and pulse oximetry cables with this pulse oximeter. Other sensors or pulse oximetry cables may cause improper N-595 performance.



WARNING: Do not attach any cable to the *OxiMAX* sensor port connector that is intended for computer use.



WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO₂ *OxiMAX* sensor. Inspect the *OxiMAX* sensor site periodically as directed in the *OxiMAX* sensor directions for use.



WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, *OxiMAX* sensor application errors, and certain patient conditions.



WARNING: Do not immerse or wet the *OxiMAX* sensor.



WARNING: Do not lift the pulse oximeter by the pulse oximetry cable or power cord because the cable or cord could disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.



Caution: The *OxiMAX* sensor disconnect error message and associated alarm indicate that the *OxiMAX* sensor is either disconnected or the wiring is faulty. The user should check the *OxiMAX* sensor connection and, if necessary, replace the *OxiMAX* sensor, pulse oximetry cable, or both.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

For a complete and up-to-date listing of all *OxiMAX* sensors applicable to the N-595, refer to the Sensor Accuracy Grid posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

When selecting an *OxiMAX* sensor, consider the patient's weight and activity level, the adequacy of perfusion, and the available *OxiMAX* sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information refer to Table 7 on page 101 or contact your local Nellcor representative. Refer to *OxiMAX Sensor Performance Considerations* on page 113, for more information on *OxiMAX* sensor performance.

Sensors and
Accessories

Table 7: Nellcor *OxiMAX* Sensor Models and Patient Sizes

<i>OxiMAX</i> Sensor	Model	Patient Size
<i>OxiMAX</i> MAX-FAST adhesive reflectance oxygen sensor	MAX-FAST	>10 kg

Table 7: Nellcor *OxiMAX* Sensor Models and Patient Sizes

<i>OxiMAX</i> Sensor	Model	Patient Size
<i>OxiMAX</i> oxygen sensor (Sterile, single-use only)	MAX-N	<3 or >40 kg
	MAX-I	3 to 20 kg
	MAX-P	10 to 50 kg
	MAX-A	>30 kg
	MAX-AL	>30 kg
	MAX-R	>50 kg
<i>OxiMAX Durasensor</i> [®] oxygen sensor (Reusable, nonsterile)	DS-100A	>40 kg
<i>OxiMAX Oxiband</i> [®] oxygen sensor (Reusable with adhesive nonsterile)	OXI-A/N	<3 or >40 kg
	OXI-P/I	3 to 40 kg
<i>OxiMAX OxiCliq</i> [®] oxygen sensors (Sterile, single-use only)	P	10 to 50 kg
	N	<3 or >40 kg
	I	3 to 20 kg
	A	> 30 kg
<i>OxiMAX Dura-Y</i> [®] multisite oxygen sensor (Reusable, nonsterile)	D-YS	>1 kg
For use with the Dura-Y sensor:		
Ear clip (Reusable, nonsterile)	D-YSE	>30 kg
<i>Pedi-Check</i> [™] pediatric spot-check clip (Reusable, nonsterile)	D-YSPD	3 to 40 kg

The pulse oximetry cable DOC-10 connects the N-595 pulse oximeter with the patient *OxiMAX* sensor.

OxIMAX Sensor Features

OxIMAX sensor features are different for *OxIMAX* sensors at a different revision level and by *OxIMAX* sensor type (adhesive, recycled, and reusable). The revision level of an *OxIMAX* sensor is located on the *OxIMAX* sensor plug.

Table 8: *OxIMAX* Sensor Features

Feature	Adhesive Sensors	Recycled Sensors	Reusable Sensors	
	Rev. B	Rev. B	Rev. A	Rev. B
<i>OxIMAX</i> Sensor Event Record	Yes	No	No	No
Sensor Messages	Yes	Yes	No	Yes
Sensor ID Message	Yes	Yes	Yes	Yes

Sensors and Accessories

Biocompatibility Testing

Biocompatibility testing has been conducted on Nellcor *OxIMAX* sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The *OxIMAX* sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

Optional Accessories


Several mounting configurations, a carrying case, and a utility basket are offered with the N-595. Contact Nellcor's Technical Services Department or your local Nellcor representative for information about these accessories.

- GCX Mounting Plate. See Figure 7 on page 105.

- GCX Poly-mount (vertical wall mount with 19-inch channel). See Figure 8 on page 106.
- GCX Poly-mount (horizontal wall mount with rail adapter). See Figure 9 on page 107.
- GCX Poly-mount Roll Stand. See Figure 10 on page 108.
- GCX Utility Basket. See Figure 11 on page 109.
- Soft-Sided Carrying Case. See Figure 12 on page 110.

Accessories for the N-595 are also listed on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Apartweb/main/PartAcceMenu.html



Sensors and
Accessories

GCX Mounting Plate

An optional mounting plate is available from Nellcor for the N-595. This mounting plate fits standard, commercially available GCX mount brackets, and is used to securely mount the N-595 to a wall bracket or a roll stand.

The mounting plate attaches to the bottom of the N-595 pulse oximeter as shown in Figure 7 on page 105. For further instructions regarding connecting the mounting plate to GCX brackets, refer to the illustrated directions for use included with the GCX mounting plate.

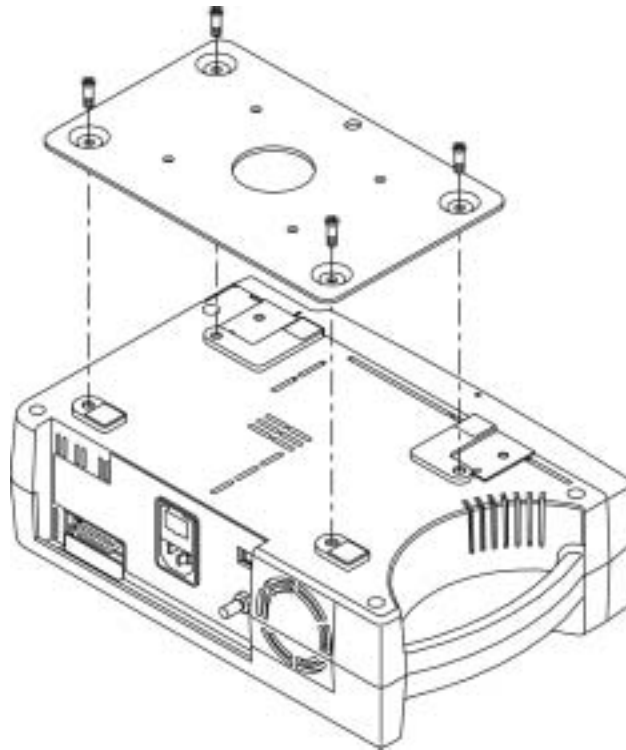


Figure 7: GCX Mounting Plate



GCX Poly-Mount (vertical wall mount with 19-inch channel)

An optional vertical wall mount with 19-inch channel is available from Nellcor for the N-595 pulse oximeter.

The vertical wall mount with 19-inch channel attaches to the N-595 pulse oximeter GCX mounting plate as shown in Figure 8 on page 106. For further instructions regarding connecting the vertical wall mount with 19-inch channel, refer to the illustrated directions for use included with the vertical wall mount with 19-inch channel.

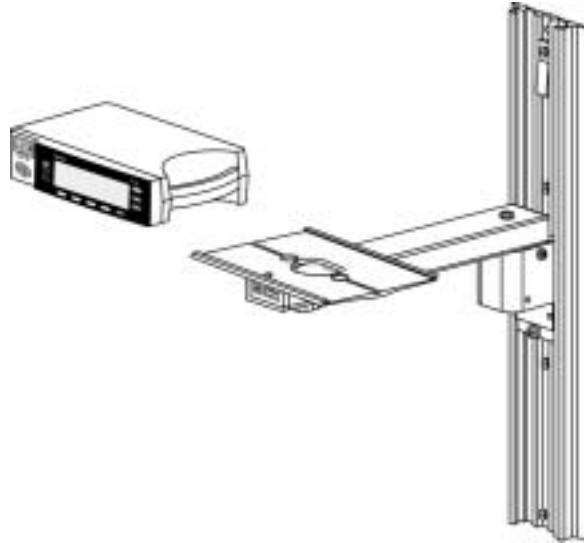


Figure 8: GCX Poly-Mount (vertical wall mount with 19-inch channel)

GCX Poly-Mount (horizontal wall mount with rail adapter)

An optional horizontal wall mount with rail adapter is available from Nellcor for the N-595 pulse oximeter.

The horizontal wall mount with rail adapter attaches to the N-595 pulse oximeter GCX mounting plate as shown in Figure 9 on page 107. For further instructions regarding connecting the horizontal wall mount with rail adapter, refer to the illustrated directions for use included with the horizontal wall mount with rail adapter.

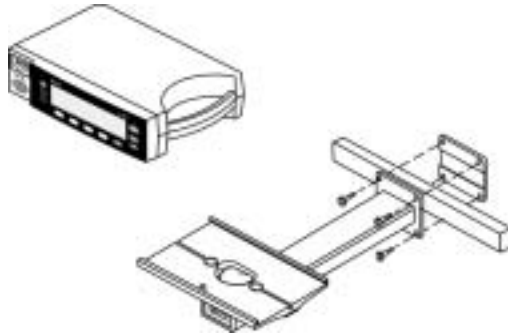


Figure 9: GCX Poly-mount (horizontal wall mount with rail adapter)



GCX Poly-Mount Roll Stand

An optional GCX poly-mount roll stand is available from Nellcor for the N-595 pulse oximeter.

The GCX poly-mount roll stand attaches to the N-595 GCX mounting plate as shown in Figure 10 on page 108. For further instructions regarding connecting the GCX poly-mount roll stand, refer to the illustrated directions for use included with the GCX poly-mount roll stand.

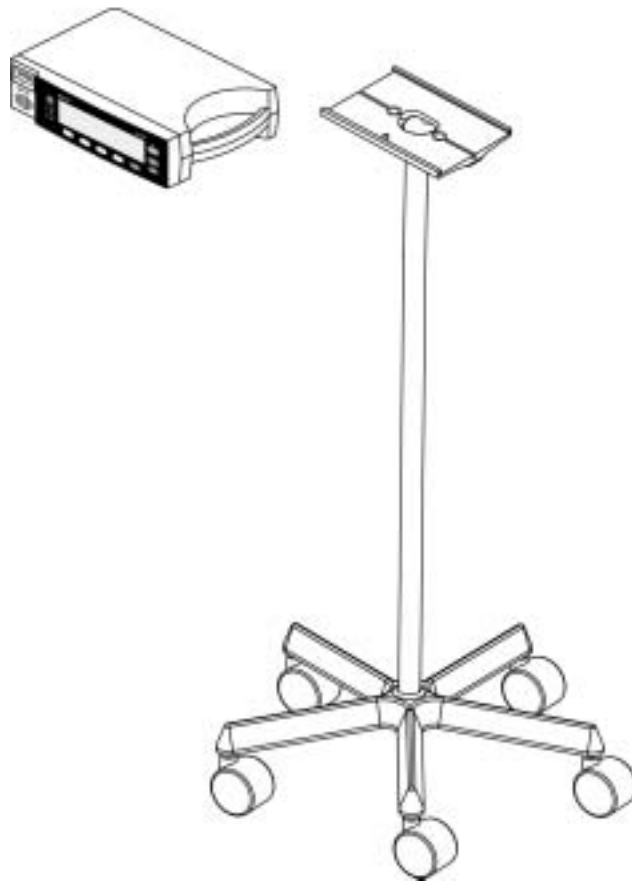


Figure 10: GCX Poly-mount Roll Stand

GCX Utility Basket

An optional GCX utility basket is available from Nellcor for the N-595 pulse oximeter. See Figure 11 on page 109.

The GCX utility basket attaches to the roll stand poly-mount. For further instructions regarding connecting the GCX utility basket, refer to the illustrated directions for use included with the GCX utility basket.



Figure 11: GCX Utility Basket



Soft-Sided Carrying Case

An optional soft-sided carrying case is available from Nellcor for the N-595 pulse oximeter. See Figure 12 on page 110. The padded carrying case protects the N-595 while transporting the monitor. The carrying case contains two pockets for *OxiMAX* sensors, cables, and operator's manual.



Figure 12: Soft-Sided Carrying Case

Sensors and
Accessories

Performance Considerations



WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, *OXIMAX* sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information:

- *Safety Information* on page 1
- *OXIMAX Sensors and Accessories* on page 99
- *Performance Considerations* on page 111

Performance Verification

The performance of the N-595 can be verified by following the procedures outlined in the Performance Verification section of the N-595 service manual. Qualified service personnel should perform these procedures before using the monitor for the first time in a clinical setting.

Sensors and
Accessories

N-595 Monitor Performance Considerations

Certain patient conditions can affect the measurements of the N-595 and cause the loss of the pulse signal.


Inaccurate measurements can be caused by:

- prolonged and/or excessive patient movement
- venous pulsations

- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation

Dysfunctional Hemoglobins

Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulphemoglobin are unable to carry oxygen. SpO₂ readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.



Sensors and Accessories

Anemia

Anemia causes decreased arterial oxygen content. Although SpO₂ readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The monitor may fail to provide an SpO₂ if hemoglobin levels fall below 5 gm/dl.

Saturation

The N-595 will display saturation levels between 1 and 100%.

Pulse Rates

The N-595 will only display pulse rates between 20 and 250 beats per minute. Detected pulse rates above 250 bpm are displayed as 250. Detected pulse rates below 20 are displayed as 0.

***OxiMAX* Sensor Performance Considerations**



WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, *OxiMAX* sensor application errors, and certain patient conditions.



WARNING: Tissue damage can be caused by incorrect application or inappropriate duration of use of an SpO₂ *OxiMAX* sensor. Inspect the *OxiMAX* sensor site as directed in the *OxiMAX* sensor directions for use.



Warning: Use only Nellcor-approved *OxiMAX* sensors and pulse oximetry cables.

Inaccurate measurements can be caused by:

- incorrect application of the *OxiMAX* sensor
- placement of the *OxiMAX* sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- prolonged and/or excessive patient movement
- intravascular dyes or externally applied coloring, such as nail polish or pigmented cream
- failure to cover the *OxiMAX* sensor site with opaque material in high ambient light conditions

Loss-of-pulse signal can occur for the following reasons:

- the *OxiMAX* sensor is applied too tightly

Sensors and
Accessories

- a blood pressure cuff is inflated on the same extremity as the one with the *OxiMAX* sensor attached
- there is arterial occlusion proximal to the *OxiMAX* sensor
- poor peripheral perfusion

Select an appropriate *OxiMAX* sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the *OxiMAX* sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the *OxiMAX* sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO₂ *OxiMAX* sensor. To prevent interference from ambient light, ensure that the *OxiMAX* sensor is properly applied, and cover the *OxiMAX* sensor site with opaque material.

Sensors and
Accessories



WARNING: Failure to cover the *OxiMAX* sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- verify that the *OxiMAX* sensor is properly and securely applied
- move the *OxiMAX* sensor to a less active site
- use an adhesive *OxiMAX* sensor that tolerates some patient motion
- use a new *OxiMAX* sensor with fresh adhesive backing

If poor perfusion affects performance, consider using the MAX-R *OxiMAX* sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This *OxiMAX* sensor may obtain measurements when peripheral perfusion is relatively poor.



Troubleshooting



WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the pulse oximeter is functioning correctly.



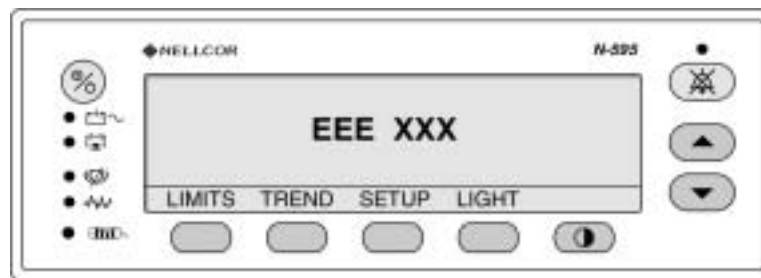
WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.



Caution: Do not spray, pour, or spill any liquid on the N-595, its accessories, connectors, switches, or openings in the chassis.

Error Codes

When the N-595 detects an error condition, it may display “EEE” followed by an error code.



Note: The “XXX” indicates that the error code number may contain up to three digits.

When an error code (other than the ones listed in Table 9 on page 118) is displayed, turn the instrument off and back on again. If the error code reappears, record it and notify service personnel.

Troubleshooting

Table 9 on page 118 lists the error codes and possible causes. When this occurs, the unit will stop monitoring, remove all information from the screen and display the message “EEE XXX,” and sound a low priority alarm. Cycling the power clears these errors.

Table 9: Error Codes

Error Code	Error Message	Action
80	DEFAULTS LOST	The current power-on default settings have been lost and returned to factory defaults. Qualified service personnel can use the service manual to restore the desired power-on default settings.
81	SETTINGS LOST	The current settings (for example, alarm limits, alarm and pulse beep volumes, alarm silence duration) have been lost and returned to power-on defaults. Turn the monitor off and back on again. If it is necessary to have settings different from the power-on default settings, turn the monitor off and back on again, and reenter the desired settings.
82	CLOCK SETTING LOST	The date and time settings have been lost. Reenter the date and time.
530	LOW BATTERY	<p>The battery is discharged to a critically low level.</p> <p>Check to ensure that the voltage selector switch on the rear panel is set to the proper voltage.</p> <p>Turn the monitor off and let it charge for approximately 10 minutes and then reattempt to turn the unit on. If the error code is still present, turn the unit off and let it continue to charge. If the monitor has been charged for 30 minutes and the error code is still present, notify service personnel.</p>

Prompts and Error Messages

Prompt/Error Messages are displayed in the menu area. Prompt messages prompt a user for a response while error messages provide information to the user. The two figures below show examples of a prompt and an error message.

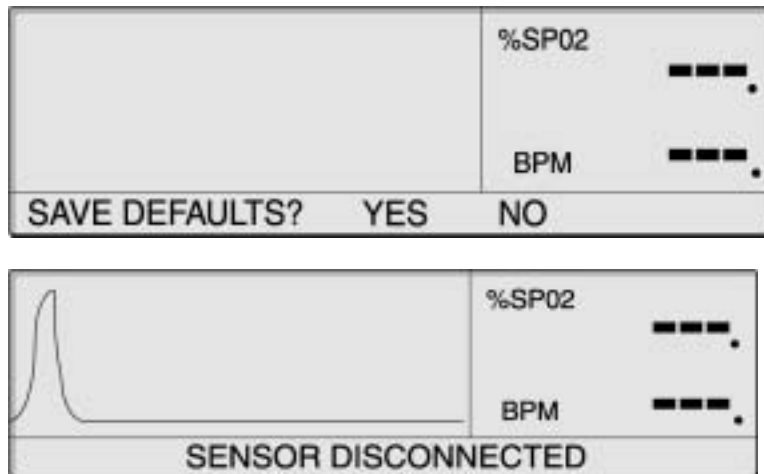


Table 10 on page 120 describes the N-595 prompt/error messages. Time-out is the maximum time that the message will remain displayed. If Time-out is None, the message will remain displayed until the condition is corrected or until an exit event occurs. Some messages will Exit on Alarm and/or Exit on Alarm Silence button press. Messages are prioritized so that more important messages will overwrite lower priority messages. Messages of the same priority will be displayed in order of occurrence. For multiple messages, lower priority messages will be displayed when higher priority conditions are cleared. The highest priority is 1 and the lowest is 3. Messages

that are advisory will be centered on the display. Prompts are those messages requiring a response (yes or no) and will be left justified.

Table 10: Prompt/Error Messages

Message	Time-out (sec.)	Exit on Alarm	Exit on Alarm Silence	When Displayed	How Cleared
CLOCK SETTING LOST	None	No	No	If the N-595 detects that the real time clock has stopped running. This will occur when both battery and AC power are lost.	After the monitor is power-cycled.
DATA IN SENSOR	5	No	Yes	When a sensor containing data is connected to the monitor.	On time-out, sensor disconnect, or pressing the ALARM SILENCE button, whichever comes first.
DATA TYPE SPO2+BPM	5	No	Yes	When a blank event sensor is connected to a monitor with event data type set to SPO2+BPM.	On time-out, sensor disconnect, or pressing the ALARM SILENCE button, whichever comes first.
DATA TYPE: SPO2	5	No	Yes	When a blank event sensor is connected to a monitor with event data type set to SPO2.	On time-out, sensor disconnect, or pressing the ALARM SILENCE button, whichever comes first.

Troubleshooting

Table 10: Prompt/Error Messages

Message	Time-out (sec.)	Exit on Alarm	Exit on Alarm Silence	When Displayed	How Cleared
DEFAULTS LOST	None	No	No	If the N-595 detects that power-on settings have been lost.	After the monitor is power-cycled.
DELETE TRENDS?	10	Yes	Yes	When the user attempts to delete trend data from memory by pressing the DELETE softkey.	After the user responds to the prompt.
LOW BATTERY	None	No	Yes (1)	When the monitor is on battery power and the battery charge is low.	When the monitor is connected to AC power or when the low battery is acknowledged by pressing the ALARM SILENCE button.
(1) The first press of the Alarm Silence softkey will silence any audible tone and the second press will clear the message.					
READING TRENDS ...	None	Yes	Yes	When the N-595 needs more than 4 to 6 seconds to retrieve trend data from memory.	When sensor data is completely retrieved or ABORT is selected.
SENSOR DISCONNECTED	None	No	Yes ¹	When the sensor is disconnected from the monitor.	When the sensor is reconnected or when the sensor disconnection is acknowledged by pressing the ALARM SILENCE button.

Troubleshooting

Table 10: Prompt/Error Messages

Message	Time-out (sec.)	Exit on Alarm	Exit on Alarm Silence	When Displayed	How Cleared
SENSOR TYPE	5	No	No	First message displayed when a sensor is connected to the monitor.	Time-out

Corrective Action

If you experience a problem while using the N-595 and are unable to correct it, contact qualified service personnel or your local Nellcor representative. The

N-595 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

The current copy of the N-595 service manual is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Following is a list of possible errors and suggestions for correcting them.

1. There is no response to the ON/STANDBY button.

- Ensure that the supply voltage selector switch is set to the proper voltage.
- A fuse may be blown. Notify service personnel to check and, if necessary, replace the fuse.
- If operating on battery power, the battery may be missing or discharged. If the battery is discharged, charge the battery, see *Operating the N-595 on Battery Power* on

page 21. If the battery will not charge, notify service personnel to replace the battery.

2. One or more display elements or indicators do not light during the power-on self-test.

- Do not use the N-595; contact qualified service personnel or your local Nellcor representative.

3. The monitor is operating on battery power, even though it is connected to AC.

- Ensure that the supply voltage selector switch is set to the proper voltage.
- Make sure that the power cord is properly connected to the N-595.
- Check to see if power is available to other equipment on the same AC circuit.

4. The Pulse Search Indicator is lit for more than 10 seconds (before any measurements are taken).

- Check the *OxiMAX* sensor directions for use to determine if an appropriate *OxiMAX* sensor is being used and if it is applied properly. Check *OxiMAX* sensor and pulse oximetry cable connections. Test the *OxiMAX* sensor on someone else. Try another *OxiMAX* sensor or pulse oximetry cable.
- Perfusion may be too low for the N-595 to track the pulse. Check the patient. Test the instrument on someone else. Change the *OxiMAX* sensor site. Try another type of *OxiMAX* sensor.

Troubleshooting

- Excessive patient motion may be preventing the N-595 from tracking the pulse. Keep the patient still, if possible. Verify that the *OxiMAX* sensor is securely applied, and replace it if necessary. Change the *OxiMAX* sensor site. Use a type of *OxiMAX* sensor that tolerates more patient movement; for example, an adhesive *OxiMAX* sensor.
- The *OxiMAX* sensor may be too tight, there may be excessive ambient light, or the *OxiMAX* sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the *OxiMAX* sensor, as necessary.
- Excessive environmental motion or electromagnetic interference may be preventing the N-595 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

5. The Pulse Search Indicator lights after successful measurements have been made.

- Check the patient.
- Perfusion may be too low for the N-595 to track the pulse. Test the instrument on someone else. Change the *OxiMAX* sensor site. Try another type of *OxiMAX* sensor.
- Excessive patient motion may be preventing the N-595 from tracking the pulse. Verify that the *OxiMAX* sensor is securely applied and replace it if necessary. Change the *OxiMAX* sensor site. Use a type of *OxiMAX* sensor that tolerates more patient movement; for example, an adhesive *OxiMAX* sensor.
- The *OxiMAX* sensor may be too tight, there may be excessive ambient light, or the *OxiMAX* sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the *OxiMAX* sensor, as necessary.

- Excessive environmental motion or electromagnetic interference may be preventing the N-595 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

6. The letters EEE, followed by a number, appear on the display.

- This is an error code. To confirm, press the ON/STANDBY button to turn the monitor off, then press the button again to turn it back on. If the display shows the error code once again, record the number and provide that information to qualified service personnel, or your local Nellcor representative.
- Error Code “EEE 4” is displayed when the battery is discharged to a critically low level. Check to ensure that the voltage selector switch on the rear panel is set to the proper voltage for your location.
- Turn the monitor off and let it charge for about 10 minutes and then turn the unit back on. If the error code is still present, turn the unit off and let it continue to charge. If the monitor has been charged for 30 minutes and the error code is still present, notify service personnel.

EMI (Electro-magnetic Interference)



Caution: This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-1-2 (second edition), EN60601-1-2, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones,

Troubleshooting

mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device.

The N-595 is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The N-595 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative.

Obtaining Technical Assistance

For technical information and assistance, or to order parts or a service manual, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the N-595.

When calling Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative, you may be asked to tell the representative the software version number of your N-595.

The software version appears in the monitor display each time the monitor successfully completes the power-on self-test. Write the number down and have it available whenever requesting technical assistance.



The current copy of this manual and the N-595 service manual are available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

***OxiMAX* Sensor Message Setup**

The *OxiMAX* sensor message setup display allows the user to enable or disable the *OxiMAX* sensor message feature. When disabled, neither the "SENSOR NOT POSTING" nor the "RECOMMENDED ACTION" messages will be displayed.

With the monitor in the normal monitoring mode:

- | | |
|---|------------------------------|
| SETUP | 1. Press the SETUP softkey. |
|  | |
| SENSOR | 2. Press the SENSOR softkey. |
|  | |

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3. Press the MSG softkey.

MSG



SENSOR MESSAGES		%SP02	---
ENABLED	<input type="checkbox"/> YES	BPM	---
BACK		EXIT	



4. Press the ADJUST UP or ADJUST DOWN button to toggle the ENABLE message.

EXIT



5. Press the EXIT softkey.

Troubleshooting

Maintenance

Follow local governing ordinance and recycling instructions regarding the disposal or recycling of the N-595 and accessories.

Returning the N-595

Contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative for shipping instructions including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the *OxiMAX* sensor or other accessory items with the monitor. Pack the N-595 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the N-595 by any shipping method that provides proof of delivery.

Service



WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

The N-595 requires no calibration.

The battery should be replaced at least every 24 months. Refer to the N-595 service manual for the battery changing procedure.

If service is necessary, contact qualified service personnel or your local Nellcor representative.

Troubleshooting

Periodic Safety Checks

It is recommended that the following checks be performed every 24 months.

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.

Cleaning



Caution: Do not spray, pour, or spill any liquid on the N-595, its accessories, connectors, switches, or openings in the chassis.

For *surface-cleaning* and *disinfecting* the monitor, follow your institution's procedures or:

- The N-595 may be *surface-cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the monitor.
- The N-595 may be *disinfected* using a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

Before attempting to clean an SpO₂ *OxiMAX* sensor, read the directions for use enclosed with the *OxiMAX* sensor. Each *OxiMAX* sensor model has cleaning instructions specific to that *OxiMAX* sensor.

Follow the *OxiMAX* sensor cleaning and disinfecting procedures in the particular *OxiMAX* sensor's directions for use.

Menu Structure

N-595 Menu Description

The N-595 menu and hierarchy are outlined below. The user chooses the type of trend data to view by selecting either Monitor trend or Sensor trend data in the Trend menu. Sensor sub-menu choices differ depending on what type of in-sensor data is stored in the sensor chip, such as, event or loop.

The menu structure includes BACK softkey options that allow the user to move back to the previous menu level without exiting the Trend menu entirely. Trend data must be compiled on entry/reentry to the Trends menu. When the softkeys are available, both BACK and EXIT options are available. The BACK softkey goes to the previous level and the EXIT softkey goes to the main menu. If only one space is available the BACK Softkey is included, this may require going back one or two levels to get to an EXIT softkey.

The BACK and EXIT softkeys are positioned on the right-most softkeys, respectively.

The below menu structure identifies:

- **BOLDFACE TYPE** — softkey title as displayed on the monitor
- Underlined Text — description of the softkey menu item
- *Italicized Text* — the destination of the BACK and EXIT softkeys

(Main Menu)

LIMITS (Limits Menu)

- **SELECT**
- **NEO**

Troubleshooting



- **ADULT**
- **EXIT** (to Main menu)
- **TREND** (Trend Menu)
- **MON** (Monitor Menu)
- **VIEW** (Monitor Trend View Menu)
- **DUAL**
- **SPO2**
- **PULSE**
- **NEXT** (History/Amplitude Menu)
- **HIST** (Delete/Print2 Menu)
- **DELETE** (delete Trends)
- "DELETE TRENDS"
- **YES** (return to Main menu)
- **NO** (back to Delete/Print menu)
- **PRINT**
- **BACT** (back to Hist/Amp menu)
- **EXIT** (to Main menu)
- **AMP** (Amplitude Menu)
- **BACK** (back to Hist/Amp menu)
- **EXIT** (to Main menu)
- **BACK** (back to Monitor Trend View menu)
- **EXIT** (to Main menu)
- **ZOOM** (Monitor Trend Zoom Menu)
- **TIME** (for current view, cycle through 48h, 36h, 12h, 8h, 4h, 2h, 1h, 30m, 15m, 40s, 20s)
- **SCALE** (for current view, cycle through ± 5 , ± 10 , ± 15 , ± 20 , ± 25 , ± 30 , ± 35 , ± 40 and ± 50 of the max and min. values under the cursor, default to 10 to 100 if there is no data point under the cursor)
- **AUTO** (based on all of the graphed trend data: maximum value, rounded up to nearest multiple of 10, minimum value, rounded down to nearest multiple of 10 minus 10)
- **BACK** (back to Monitor menu)
- **NEXT** (Delete/Print1 Menu)
- **DELETE**
- "DELETE TRENDS?"
- **YES** (to Main menu)
- **NO** (back to Delete/Print1 menu)
- **PRINT**
- **BACK** (back to Monitor menu)
- **EXIT** (to Main menu)
- **BACK** (back to Trend menu)
- **SENSOR** (Sensor/Event Menu)

(if Event data is in the sensor, the following menu, the Screen will remain in the appropriate state until the next menu selection is made)

- - **GRAPH** (Graph Menu) (*display events #1-N, in inverse chronological order; up/down also scroll through events in order*)
 - - - < (*show previous graph, only available when there is a previous graph*)
 - - - > (*show next graph, only available when there is a next graph*)
 - - - **PRINT**
 - - - **BACK** (*back to Sensor menu*)
 - - **TABLE** (Table Menu)
 - - - ^ (*show previous table, only available when there is a previous graph; bottom/top line repeats in new table*)
 - - - v (*show next table, only available when there is a next graph; bottom/top line repeats in new table*)
 - - - **PRINT**
 - - - **BACK** (*back to Sensor menu*)
 - - - **EXIT** (*to Main menu*)
- - (Sensor/Loop Menu) (*If continuous-Loop data is in the sensor, the following will be displayed*)
 - - **VIEW** (Sensor Trend View Menu)
 - - - **DUAL** (*shows SPO2+BPM*)
 - - - **SPO2**
 - - - **PULSE**
 - - - **ZOOM** (*cycle through 2h. 1h, 30m, and 15m for current view*)
 - - **PRINT**
 - - **BACK** (*to Trend menu*)
 - **EXIT** (*to Main menu*)
- **SETUP** (Setup Monitor Menu)
 - **VIEW** (Setup View Menu)
 - - **PLETH**
 - - **BLIP**
 - - **BACK** (*back to Setup menu*)
 - - **EXIT** (*to Main menu*)
 - **SENSOR** (Setup Sensor Menu)
 - - **DATA** (*On-screen options for SENSOR-R (Write-once Sensor) sensor are: "SPO2, SPO2+BPM, DEFAULT." On-screen options for SENSOR-RW (rewritable sensor) are: "SPO2, SPO2+BPM, DEFAULT." SELECT toggles SENSOR-R or SENSOR-RW sensor type; up/down keys scroll*)

Troubleshooting

through options in order.) The SENSOR-R feature supports all of the current OxiMax sensors.

- - - **SELECT**
- - - **BACK** (back to Setup Sensor menu)
- - - **EXIT** (to Main menu)
- - **MSG** (Sensor Set Message Menu)
- - - **BACK** (back to Setup Sensor menu)
- - - **EXIT** (to Main menu)
- **NEXT** (Clock/Language Menu)
- - **CLOCK** (Clock Menu)
- - - **SET** (Clock Set Menu)
- - - - **SELECT** (press select to toggle through hours, minutes, seconds, month, day, year; use up/down buttons to set each selection)
- - - - **BACK** (back to Clock/Language menu)
- - - - **EXIT** (to Main menu)
- - **LANG** (Language Setup Menu) (use up/down buttons to toggle though languages)
- - - **BACK** (back to Clock/Language menu)
- - **NEXT** (Communication/Nurse Call Menu)
- - - **COMM** (Communication Port Configuration Menu)
- - - - **SELECT**
- - - - **BACK** (back to Communication/Language menu)
- - - - **EXIT** (to Main menu)
- - - **NCALL** Nurse Call Menu)
- - - - **NORM +**
- - - - **NORM -**
- - - - **BACK** (back to Communication/Nurse Call menu)
- - - - **EXIT** (to Main menu)
- - - **NEXT** (Analog/Mode Menu)
- - - - **ANALOG** (Analog Voltage Select Menu)
- - - - - **0 VOLT**
- - - - - **1 VOLT**
- - - - - **STEP**
- - - - - **BACK** (back to Analog/Mode menu)
- - - - **MODE** (Mode Menu)
- - - - - **BACK** (back to Analog/Mode menu)
- - - - - **EXIT** (to Main menu)
- - - - **BACK** (back to Communication/Nurse Call menu)
- - - - **EXIT** (to Main menu)
- - - **BACK** (back to Clock/Language menu)
- - **BACK** (back to Setup menu)
- **EXIT** (to Main menu)
- LIGHT** (Turns the display backlight on or off)

SatSeconds

Describing *SatSeconds*

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an audible alarm immediately sounds. When the %SpO₂ level fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarms can be distracting.

The N-595 pulse oximeter utilizes Nellcor *SatSeconds* alarm management technique. With the *SatSeconds* technique, upper and lower alarm limits are set in the same way as with traditional alarm management. The clinician also sets a *SatSeconds* limit that allows the monitoring of %SpO₂ below the selected low alarm limit for a period of time before an audible alarm sounds.

The *SatSeconds* limit controls the time that the %SpO₂ level may fall outside the alarm before an audible alarm sounds.

The method of calculation is as follows:

The number of percentage points that the %SpO₂ falls outside of the alarm limit is multiplied by the number of seconds that the %SpO₂ level remains outside that limit. This can be stated as an equation:

$$\text{Points} \times \text{Seconds} = \text{SatSeconds}$$

Where:

Points = %SpO₂ percentage points outside of the limit

Seconds = number of seconds the %SpO₂ remains at that point outside of the limit

The alarm response time, assuming a *SatSeconds* limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the %SpO₂ level drops to 88 (2 points) and remains there for a period of 2 seconds (2 points x 2 seconds = 4 *SatSeconds*). The %SpO₂ then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting *SatSeconds* are:

%SpO ₂	Seconds	<i>SatSeconds</i>
2 x	2 =	4
4 x	3 =	12
6 x	6 =	36
Total <i>SatSeconds</i> =		52

After approximately 10.9 seconds the *SatSeconds* alarm would sound, because 50 *SatSeconds* had been exceeded. See the arrow (↑) in Figure 13 on page 136.

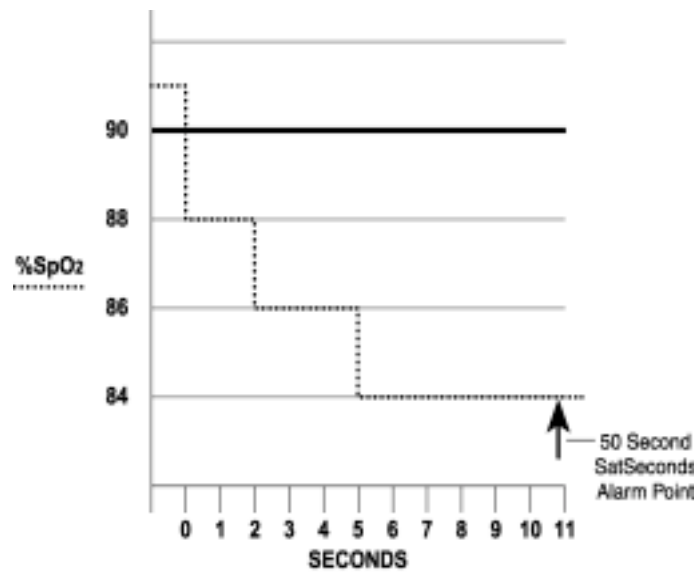


Figure 13: Alarm Response with *SatSeconds*

Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, the %SpO₂ levels may fluctuate above and below the alarm limit, re-entering the non-alarm range several times.

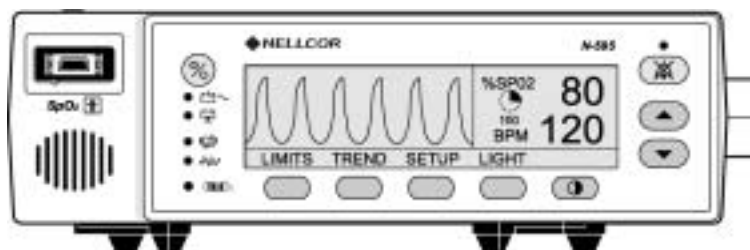
During such fluctuations, the N-595 pulse oximeter integrates the number of %SpO₂ points, both positive and negative, until either the *SatSeconds* limit (*SatSeconds* time setting) is reached, or the %SpO₂ level returns to within a normal range and remains there.

SatSeconds “Safety Net”

The *SatSeconds* “Safety Net” is for patients with saturation levels having frequent excursions below the limit, but not staying below the limit long enough for the *SatSeconds* time setting to be reached. When 3 or more limit violations occur within 60 seconds, an alarm will sound even if the *SatSeconds* time setting has not been reached.

SatSeconds Display

When the N-595 *SatSeconds* technology detects an SpO₂ value outside the alarm limit, the *SatSeconds* indicator (the circular graph located on the right side of the display, adjacent to the SpO₂ reading) begins to “fill” clockwise. When the SpO₂ value is within the set limits, the *SatSeconds* indicator will empty counter-clockwise.



When the indicator is completely filled, indicating that the *SatSeconds* setting has been reached, an audible alarm sounds and the displayed %SpO₂ rate flashes. As with traditional alarm management,

the audible alarm may be silenced by pressing the ALARM SILENCE button.

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Factory Defaults

The N-595 is shipped with factory default settings. Authorized technical personnel using the procedures described in the N-595 service manual can change default settings.

Neonate Default Settings

Table 11: Neonate Factory Defaults

Parameter	Setting
Monitoring Mode	Neo
%SpO2 Lower Alarm Limit	80%
%SpO2 Upper Alarm Limit	95%
Allow silence duration to be set to OFF	Yes
Alarm Silence Duration	60 seconds
Alarm Silence Reminder	Enabled
Alarm Volume	7 of 10
Data Port Baud Rate	9600
Data Port Protocol	ASCII
Display Contrast	Midrange
Display Format	Pleth
Language	English
Nurse Call Polarity	Normally Low
Pulse Beep Volume	4 of 10
Pulse Rate Lower Alarm Limit	90 beats per minute

Table 11: Neonate Factory Defaults

Parameter	Setting
Pulse Rate Upper Alarm Limit	190 beats per minute
Response Mode	Normal
<i>SatSeconds</i>	Off
Trend Display	%SpO2
Trend Scale	2 hours

Adult Default Settings

Table 12: Adult Factory Defaults

Parameter	Setting
Monitoring Mode	Adult
%SpO2 Lower Alarm Limit	85%
%SpO2 Upper Alarm Limit	100%
Allow silence duration to be set to OFF	Yes
Alarm Silence Duration	60 seconds
Alarm Silence Reminder	Enabled
Alarm Volume	7 of 10
Data Port Baud Rate	9600
Data Port Protocol	ASCII
Display Contrast	Midrange
Display Format	Pleth
Language	English
Nurse Call Polarity	Normally Low

Table 12: Adult Factory Defaults

Parameter	Setting
Pulse Beep Volume	4 of 10
Pulse Rate Lower Alarm Limit	40 beats per minute
Pulse Rate Upper Alarm Limit	170 beats per minute
Response Mode	Normal
<i>SatSeconds</i>	Off
Trend Display	%SpO ₂
Trend Scale	2 hours

Principles of Operation

Oximetry Overview

The N-595 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMAX* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMAX* sensor contains a dual light source and a photo detector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO₂).

Because a measurement of SpO₂ is dependent upon light from the *OxiMAX* sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, *OxiMAX* sensor application, and patient conditions is contained throughout this manual.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OxiMAX* sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen

saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO₂ measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the *OxiMAX* sensor's red LED to accurately measure SpO₂.

During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual *OxiMAX* sensor's red LED; these coefficients are then used to determine SpO₂.

Additionally, to compensate for differences in tissue thickness, the light intensity of the *OxiMAX* sensor's LEDs is adjusted automatically.

Functional versus Fractional Saturation

This pulse oximeter measures functional saturation – oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation – oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\% \text{ carboxyhemoglobin} + \% \text{ methemoglobin})} \times 100$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. See Figure 14 on page 145.

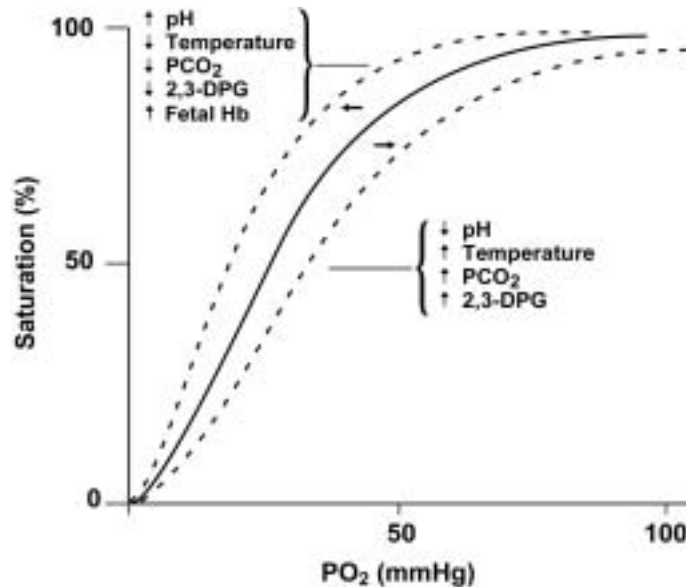


Figure 14: Oxyhemoglobin Dissociation Curve

OxiMAX Technology

The N-595 pulse oximeter is designed to use Nellcor *OxiMAX* brand sensors, which integrate the *OxiMAX* technology. These *OxiMAX* sensors can be identified by their deep lavender/blue plug color. All *OxiMAX* sensors contain a memory chip carrying information about the *OxiMAX* sensor, which the oximeter needs for correct operation, including the *OxiMAX* sensor's calibration data, model type,

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troubleshooting codes, and error detection data. This unique oximetry architecture enables development of new sensors as well as several new features with the *OxiMAX* sensor N-595.

When an *OxiMAX* sensor is connected to the N-595, the pulse oximeter will first read the information in the *OxiMAX* sensor memory chip, checks it to make sure that there are no errors, and then loads the data to begin monitoring. As the pulse oximeter reads the information, it displays the *OxiMAX* sensor model number. This process only takes a couple of seconds. The *OxiMAX* sensor model number disappears after 5 seconds.

Pulse oximeters containing *OxiMAX* technology, including the N-595, use calibration data contained in the *OxiMAX* sensor in calculating the patient's SpO₂. Consult the *OxiMAX* sensor accuracy grid card included with the pulse oximeter for specific accuracy information for the N-595 with different Nellcor *OxiMAX* sensors.

The N-595 uses the information in the *OxiMAX* sensor to tailor troubleshooting messages for the clinician. The *OxiMAX* sensor contains coding that tells the pulse oximeter what kind of *OxiMAX* sensor is being used. When deciding what messages to display, the pulse oximeter takes into account the *OxiMAX* sensor type and recommended patient site for that model.

Specifications

Performance

Measurement Range	
SpO2	1% to 100%
Pulse Rate	20 beats per minute (bpm) to 250 bpm
Perfusion Range	0.03% to 20%

Accuracy and Motion Tolerance	
Saturation	
Without Motion - Adults ¹	70 to 100% ± 2 digits
Without Motion - Neonate ¹	70 to 100% ± 3 digits
With Motion - Adults and Neonates ²	70 to 100% ± 3 digits
Low Perfusion ³	70 to 100% ± 2 digits
Pulse Rate	
Without Motion ^{1, 2, 3}	20 to 250 bpm ± 3 digits
With Motion ²	normal physiologic range (55 - 125 bpm) ± 5 digits
Low Perfusion ³	20 to 250 bpm ± 3 digits

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Accuracy and Motion Tolerance

¹ Adult specifications are shown for *OxiMAX* MAX-A and MAX-N sensors with the N-595. Neonate specifications are shown for *OxiMAX* MAX-N sensors with the N-595. Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid. The Sensor Accuracy Grid is shipped with the monitor. The latest version of the Sensor Accuracy Grid is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

² Applicability: *OxiMAX* MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

³ Specification applies to monitor performance.

Display Update Interval

2 seconds

Electrical

Instrument

Power Requirements	rated at 108 to 132 volts AC (nominal 120 VAC) or 220 to 240 volts AC (nominal 230 VAC), 20 volt/amps to be compliant with IEC 60601-1 sub-clause 10.2.2
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Fuses	qty 2, 0.5 A, 250 volts, slow-blow, IEC (5 x 20 mm)
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Battery

The battery provides at least 2 hours of battery life when new and fully charged with no alarms, no serial data, no analog output, no nurse call output, with backlight on while using a pulse simulator set for 224 bpm, high light and low modulation.

Battery	
Type	Lead acid
Voltage	6 Volts DC
Recharge	<ul style="list-style-type: none"> 14 hours with N-595 turned off 18 hours with N-595 operating
Shelf Life	<ul style="list-style-type: none"> 2 months, new fully charged battery After 2 months storage, the N-595 will run for 50% of stated battery life
Complies With	91/157/EEC

OxiMAX Sensors	
Wavelength and Power	The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15 mW.

Environmental Conditions

Operation	
Temperature	5 °C to 40 °C (41 °F to 104 °F)
Altitude	-390 m to 3,012 m (-1,254 ft. to 9,882 ft.)
Atmospheric Pressure	70 kPa to 106 kPa (20.6 in. Hg to 31.3 in. Hg)

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Operation

Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5
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Transport and Storage (not in shipping container)

Temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Altitude	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa (14.7 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

Transport and Storage (in shipping container)

Temperature	-20 °C to 70 °C (-4 °F to 158 °F)
Altitude	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa (14.7 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

OxiMAX Sensor Power Dissipation

Sensor	Dissipation
OxiMAX MAX-N	52.5 mW
OxiMAX MAX-I	52.5 mW

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OxiMAX Sensor Power Dissipation

Sensor	Dissipation
<i>OxiMAX</i> MAX-P	52.5 mW
<i>OxiMAX</i> MAX-A	52.5 mW
<i>OxiMAX</i> MAX-AL	52.5 mW
<i>OxiMAX</i> MAX-R	52.5 mW
<i>OxiMAX OxiBand</i> OXI-A/N	52.5 mW
<i>OxiMAX OxiBand</i> OXI-P/I	52.5 mW
<i>OxiMAX Durasensor</i> DS-100A	52.5 mW
<i>OxiMAX OxiCliq</i> P	52.5 mW
<i>OxiMAX OxiCliq</i> N	52.5 mW
<i>OxiMAX OxiCliq</i> I	52.5 mW
<i>OxiMAX OxiCliq</i> A	52.5 mW
<i>OxiMAX Dura-Y</i> D-YS	52.5 mW
<i>OxiMAX</i> MAX-FAST	52.5 mW

Physical Characteristics

Weight	5.8 lbs. (2.6 kg)
Dimensions	3.3 in. x 10.4 in. x 6.8 in. (8.4 cm x 26.4 cm x 17.3 cm)

Compliance

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1 (same as EN60601-1), CSA 601.1, UL 2601-1, EN865, EN/IEC 60601-1-2 (second edition)
Type of protection	Class 1 (on AC power) Internally powered (on battery power)
Degree of protection	Type BF - Applied part
Mode of operation	Continuous
N-595 resistant to liquid ingress	IEC 60601-1, sub-clause 44.6 for class IPX1 Drip-Proof equipment
Degree of Safety in presence of a flammable anaesthetic	UL 2601-1, sub-clause 5.5, Not suitable
Applied sensor label to indicate Type BF applied part	IEC 60601-1 Symbol 2 of Table DII of Appendix D
Equipotential lug symbol to indicate a potential equalization conductor	IEC 60601-1 Symbol 9 of Table DI of Appendix D
Attention symbol, consult accompanying documentation	IEC 60601-1 Symbols 14 of Table DI of Appendix D
External case made with non-conductive plastic	IEC 60601-1, sub-clause 16(a)
No holes in case top	IEC 60601-1, sub-clause 16(b)
115/230 voltage selector switch	IEC 60601-1, sub-clause 16(f)
Rigid case	IEC 60601-1, sub-clause 21(a)
Case mechanically strong	IEC 60601-1, sub-clause 21(b)
Case handle	IEC 60601-1, sub-clause 21(c)

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Item	Compliant With
N-595 resistant to rough handling	IEC 60601-1, sub-clause 21.6
N-595 tip/tilt test	IEC 60601-1, sub-clause 24.1
N-595 resistant to liquid ingress due to spills	IEC 60601-1, sub-clause 44.3 as modified by EN 865, clause 4
Environmental	IEC 60601-1, sub-clause 44.5
Cleaning	IEC 60601-1, sub-clause 44.7
Case surface made of non-toxic materials	IEC 60601-1, sub-clause 48
Case resistant to heat and fire	IEC 60601-1, sub-clause 59.2(b)
N-595 power entry module fuse holder	IEC 60601-1, sub-clause 59.3
N-595 exterior markings	IEC 60601-1, sub-clause 6.1, 6.3, and 6.4; EN 865, clause 6
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
N-595 button spacing	ISO 7250
Year of manufacture symbol	EN 980
Conductive coating and polymeric materials	UL 2601-1, clause 55
Operation during physical shock	IEC 60068-2-27 at 100 g
Operation during vibration	IEC 60068-2-6 and IEC 60068-2-34
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, IEC/EN 60601-1-2 (second edition)
Radiated and conducted emissions	EN 55011, Group 1, Class B
Harmonic emissions	IEC 61000-3-2
Voltage fluctuations/flicker emissions	IEC 61000-3-3

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Item	Compliant With
Electrostatic discharge immunity	EN 61000-4-2, level 3 table top equipment
Radiated radio-frequency electromagnetic field immunity	IEC 61000-4-3 at 3V/m
Electrical fast transient/burst immunity	IEC 61000-4-4, level 3
Surge immunity	IEC 61000-4-5, level 3; FDA Reviewer's Guide
Conducted EMI susceptibility	IEC 61000-4-6 at 3 V/m
Power frequency magnetic fields	IEC 61000-4-8 at 3 V/m
Operation with line voltage variations	IEC 61000-4-11 for Table 7
Operation with electrical line voltage variations	FDA Reviewer's Guide
Radiated magnetic field emissions	RE 101/Army/7cm of MIL-STD-461E
Magnetic field susceptibility	RS 101 in MIL-STD-461E
Quasi-static electric field susceptibility	FDA Reviewer's Guide

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Manufacturer's Declaration



WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the N-595 pulse oximeter.

Table 13: Electromagnetic Emissions

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1	The N-595 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The N-595 is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

Table 14: Electromagnetic Immunity

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-2	±8 kV air	±8 kV air	
Electric fast transient/ burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial and/or hospital environment
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	

Note: UT is the AC mains voltage prior to application of the test level.

Table 14: Electromagnetic Immunity

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U_T	<5 % U_T	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the N-595 requires continued operation during power mains interruption, it is recommended that the N-595 be powered from an uninterruptible power supply or battery.
	(>95 % dip in U_T) for 0.5 cycle	(>95 % dip in U_T) for 0.5 cycle	
	40 % U_T	40 % U_T	
	(60 % dip in U_T) for 5 cycles	(60 % dip in U_T) for 5 cycles	
	70 % U_T	70 % U_T	
	(30 % dip in U_T) for 25 cycles	(30 % dip in U_T) for 25 cycles	
	<5 % U_T	<5 % U_T	
	(95 % dip in U_T) for 5 sec.	(95 % dip in U_T) for 5 sec.	

Note: U_T is the AC mains voltage prior to application of the test level.

Table 14: Electromagnetic Immunity

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	It may be necessary to position the N-595 further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
IEC 61000-4-8			
Note: UT is the AC mains voltage prior to application of the test level.			

Table 15: Electromagnetic Immunity, RF Portable Equipment

For portable and mobile communication equipment. The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the N-595, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.			
Recommended Separation Distance			
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	$distance = 1.2\sqrt{Power}$
	80 MHz		
	800 MHz		80 MHz to 800 MHz
	3 V/m	3 V/m	$distance = 2.3\sqrt{Power}$
	800 MHz		800 MHz to 2.5 GHz
	2.5 GHz		

Note: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with survey accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the N-595 is used exceeds the applicable RF compliance level above, the N-595 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the N-595.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Interference may occur in the vicinity of equipment marked with the following symbol:



Table 15: Electromagnetic Immunity, RF Portable Equipment

For portable and mobile communication equipment. The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF	3 Vrms	3 Vrms	$distance = 1.2\sqrt{Power}$
	150 kHz		150 kHz to 80 MHz
IEC 61000-4-6	80 MHz		

Note: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with survey accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the N-595 is used exceeds the applicable RF compliance level above, the N-595 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the N-595.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Interference may occur in the vicinity of equipment marked with the following symbol:



Table 16: Recommended Separation Distances

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the N-595 (IEC 60601-1-2)

Frequency of Transmitter	26 MHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters	Separation Distance in Meters	Separation Distance in Meters
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 17: Cables

Cables and <i>OxiMAX</i> Sensors	Maximum Length	Complies With
DOC-10 pulse oximetry cable	10 ft. (3 m)	<ul style="list-style-type: none"> RF emissions, CISPR 11, Class B/Group 1
Software download cable, RS-232 serial, 15 to 9 pin "D"	10 ft. (3 m)	<ul style="list-style-type: none"> Harmonic emissions, IEC 61000-3-2 Voltage fluctuations/flicker emission, IEC 61000-3-3
Non-terminated cable, RS-232/Analog, 15 pin "D"	3.3 ft. (1 m)	<ul style="list-style-type: none"> Electrostatic discharge (ESD), IEC 61000-4-2 Electric fast transient/burst, IEC 61000-4-4
Oxinet hardwire cable	10 ft. (3 m)	<ul style="list-style-type: none"> Surge, IEC 61000-4-5
Printer cable, RS-232, 15 to 9 pin "D"	3.3 ft. (1 m)	<ul style="list-style-type: none"> Conducted RF IEC 61000-4-6 Radiated RF, IEC 61000-4-3
HP Agilent interface cable	3.3 ft. (1 m)	
GE Marquette interface cable	3.3 ft. (1 m)	
Datex-Ohmeda interface cable	3.3 ft. (1 m)	
Oxinet® II Data Cable	10 ft. (3 m)	
HP Agilent interface cable	10 ft. (3 m)	

Table 17: Cables

Cables and <i>OxiMAX</i> Sensors	Maximum Length	Complies With
<i>OxiMAX</i> sensors:		<ul style="list-style-type: none"> RF emissions, CISPR 11, Class B/Group 1
MAX-A	1.5 feet (0.5 m)	
MAX-AL	3 feet (0.9 m)	<ul style="list-style-type: none"> Harmonic emissions, IEC 61000-3-2
MAX-I	1.5 feet (0.5 m)	<ul style="list-style-type: none"> Voltage fluctuations/flicker emission, IEC 61000-3-3
MAX-N	1.5 feet (0.5 m)	
MAX-P	1.5 feet (0.5 m)	<ul style="list-style-type: none"> Electrostatic discharge (ESD), IEC 61000-4-2
MAX-R	1.5 feet (0.5 m)	<ul style="list-style-type: none"> Electric fast transient/burst, IEC 61000-4-4
	1.5 feet (0.5 m)	<ul style="list-style-type: none"> Surge, IEC 61000-4-5
<i>OxiMAX</i> <i>Oxiband</i> sensors:	3 feet (0.9 m)	<ul style="list-style-type: none"> Conducted RF IEC 61000-4-6
OXI-A/N		<ul style="list-style-type: none"> Radiated RF, IEC 61000-4-3
OXI-P/I		

Table 17: Cables

Cables and <i>OxiMAX</i> Sensors	Maximum Length	Complies With
<i>OxiMAX</i> <i>Durasensor</i> sensor	3 feet (0.9 m)	<ul style="list-style-type: none"> • RF emissions, CISPR 11, Class B/Group 1
DS-100A		<ul style="list-style-type: none"> • Harmonic emissions, IEC 61000-3-2 • Voltage fluctuations/flicker emission, IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IEC 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3

Table 17: Cables

Cables and <i>OxiMAX</i> Sensors	Maximum Length	Complies With
<i>OxiMAX</i> <i>OxiCliq</i> sensors: P N I A	OC-3 cable 3 feet (0.9 m)	<ul style="list-style-type: none"> • RF emissions, CISPR 11, Class B/Group 1 • Harmonic emissions, IEC 61000-3-2 • Voltage fluctuations/flicker emission, IEC 61000-3-3
<i>OxiMAX</i> <i>Dura-Y</i> sensors: D-YS D-YSE D-YSPD	4 feet (1.2 m)	<ul style="list-style-type: none"> • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IEC 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3

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EXHIBIT 3

A Technology Overview of the Nellcor® OxiMax® Pulse Oximetry System

Nellcor Technical Staff

Why Nellcor Developed the OxiMax Pulse Oximetry System

The introduction of the *OxiMax*® Pulse Oximetry System brought Nellcor's fifth-generation pulse oximetry technology to market and marked a fundamental shift in one of the design tenets of pulse oximeters. In the first four generations of Nellcor® pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient.

However, while developing products to meet a broader range of clinical applications and challenges, we recognized that the existing technology platform limited Nellcor, as well as all other pulse oximeter manufacturers. Historically, sensor calibration coefficients have resided within the monitor. A single calibration curve or a limited set of curves is programmed into the monitor, and sensor designs must conform to the preprogrammed data in order to accurately calculate arterial oxygen saturation (SpO_2). This conventional, "in-the-box" calibration scheme has restrained sensor inventions that could address unique patient care needs.

Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named *OxiMax*, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself.

With the *OxiMax* system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The *OxiMax* platform also expands the clinical utility of the monitor itself, because the monitor can display troubleshooting tips and other data that assists clinicians with patient care.

Principles of Pulse Oximetry and Conventional Calibration

To better understand the significance of *OxiMax* technology and what inspired Nellcor to develop it, it may be helpful to review the underlying principles of pulse oximetry.

Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry

Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.*

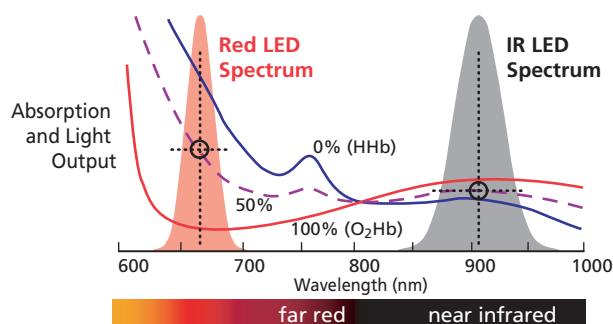


Figure 1

Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles.

* The effects of motion and other signal noise do not impact the basic calibration of pulse oximetry.

Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb , respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2 . Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra.

Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.)

At low saturation this situation is reversed. Low saturation blood (high amount of HHb , indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal.

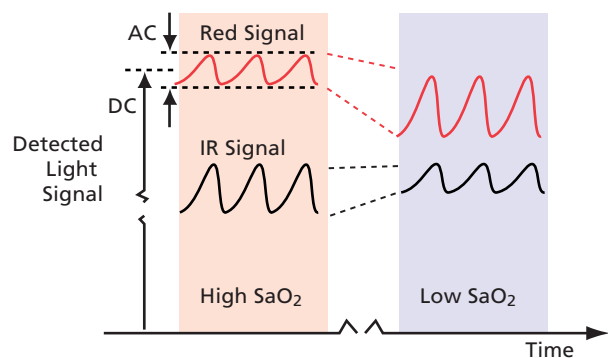


Figure 2
Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed.

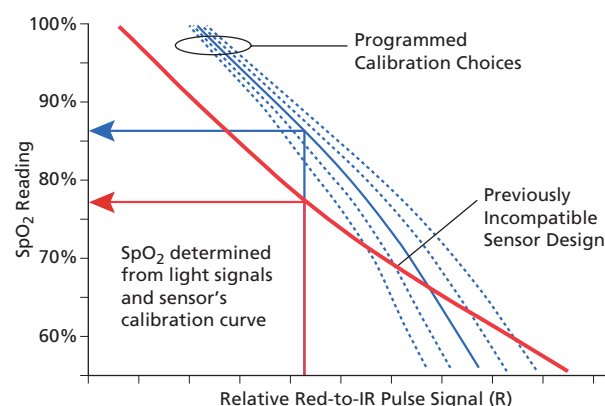


Figure 3
The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals.

Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3).

The Effect of LED Characteristics on Calibration Curves

Because the light absorption of the blood's oxygenated and, more importantly, deoxygenated hemoglobin is significantly wavelength-dependent, the relationship between R and SpO_2 strongly depends on the specific emission characteristics (e.g., color) of the sensor's LEDs.

Suppose the red LED used within a sensor is selected with a slightly different color—for example, one slightly more orange (to the left of the red LED spectrum shown in Figure 1). Light absorption by the blood (black circle) would increase compared with the previously chosen truly red emitter (following along up the dashed purple line), and the resulting apparent pulse size of the detected light signal would increase. Particularly at lower arterial blood saturation, the modulating blood volume in the tissue more greatly influences detected orange light than red light because deoxyhemoglobin absorption in this color region increases significantly as the wavelength becomes shorter.

The impact of this more orange-colored emitter is to shift and rotate the sensor's calibration curve—with more of a change at low saturation than high (see Figure 3, dotted curves to the right of the solid

blue curve). At any given true arterial saturation, the red-to-IR Modulation Ratio will be larger when using red LEDs that are more toward the orange side of the spectrum.

Accurate measurements of saturation require the calibration curve (used to translate the measured Modulation Ratio to its corresponding SpO_2 value) to correspond to the actual LED wavelengths used in the sensor, along with the other optical characteristics of the sensor that affect calibration.

LED manufacturers generally have much less control of batch-to-batch and device-to-device emitter wavelength than is required for accurate pulse oximetry measurements. Wavelength control is less of a concern for the primary uses of red LEDs—automotive tail lights, traffic stoplights, and indicator lamps on stereos, ovens, etc.—simply because the human eye cannot distinguish these subtle color differences. But pulse oximeters can make these distinctions, particularly in the red part of the spectrum. Though semiconductor manufacturers have improved their processes over the years, LED wavelength control has remained problematic for pulse oximeter manufacturers.

Accommodating LED Variance During Sensor Manufacturing

To accommodate this limited control, every pulse oximeter manufacturer must do some form of emitter wavelength characterization to achieve its accuracy specifications.

Most sensor manufacturers purchase or screen emitters to a narrow range of LED wavelengths and program into the monitor a single calibration curve that corresponds to this range. Some manufacturers use a liberal range of wavelengths with a single curve, resulting in degraded accuracy performance, particularly below 85% saturation. Nellcor has in the past used a resistor-encoding scheme in which several calibration curves are programmed into Nellcor pulse oximeters and pulse oximetry modules to span a broad range of LED wavelengths needed for high-volume sensor manufacturing.

Nellcor's resistor-calibration technique, known as RCAL, communicates to the monitor which of the curves to use. When the sensor is first connected to the oximeter, a resistor housed within the sensor connector plug is read by the oximeter to identify specifically which of the preprogrammed curves should be used to calculate SpO_2 values.

During sensor manufacturing, Nellcor measures the wavelength characteristics of every red and IR LED emitter. Emitters are sorted and placed into bins of similarly colored emitters, with each bin corresponding to an associated proper calibration curve. The RCAL system is used by the monitor to identify from a lookup table which of the preprogrammed curves to use, with specific electrical resistor values assigned to identify each bin (Figure 4). Thus, SpO_2 accuracy is maintained while using the full range of supplied emitter wavelengths. High manufacturing yield can be attained efficiently, since virtually all the emitters can be used.

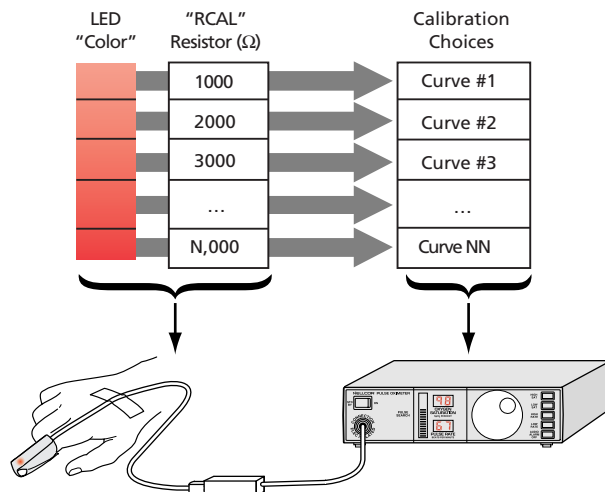


Figure 4

The color (wavelength) of each LED emitter is measured during Nellcor's sensor manufacturing process, and paired in the RCAL scheme with a corresponding electrical resistor. The monitor, in turn, measures the resistor value and uses the associated proper calibration curve for that sensor in determining SpO_2 .

Limitations of Monitor-Based Calibration

The need to predefine calibration curves to address LED wavelength variations has hindered pulse oximetry manufacturers from making technological advancements that could enhance clinical care. For instance, manufacturers may not be able to take advantage of newer high-efficiency LEDs, since their spectral properties are sufficiently different from those designed by semiconductor companies years ago. These newer LEDs offer greater versatility in oximeter designs. They can lower the power needs of oximeters, which usually translates to longer battery life, and they can dramatically increase signal strength, which helps improve monitoring performance during challenging conditions. As semiconductor manufacturers continue to improve their own

processes for fabricating state-of-the-art LEDs, Nellcor wants to be able to take advantage of their latest advancements.

Manufacturers are also constrained in creating new types of sensors, because sensor designs that do not precisely conform to the calibration curves preprogrammed in the monitor would result in degraded accuracy. Though in the Nellcor RCAL system many sensors can be developed to fit one or more of the available choices (blue curves in Figure 3), other designs may only moderately fit or miss by an amount that would result in clinically unacceptable accuracy (as depicted by the red curve in Figure 3). This limits possibilities, such as new sensors designed for more convenient placement sites on the patient.

Nellcor's RCAL calibration curves were created in the middle 1980s, based on LEDs and sensor designs of the time. New sensors developed since then have had to conform to these preprogrammed curves to ensure compatibility across the installed base of Nellcor pulse oximeters and OEM multiparameter monitors. Though not overly restrictive through the 1980s and 1990s, this "in-the-box" calibration scheme limits the ability to create new types of sensors. For pulse oximetry in the 2000s, the *OxiMax* platform allows more innovative and versatile designs.

Digital Memory Chip Is the Key to *OxiMax* Versatility

In developing the *OxiMax* Pulse Oximetry System, Nellcor focused on achieving these goals:

- Provide customers with superior levels of monitor and sensor performance.
- Create latitude for accommodating future sensor designs as patient care evolves.

The *OxiMax* system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor *OxiMax* sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every *OxiMax* sensor provides precisely the versatility Nellcor sought. The *OxiMax* platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints.

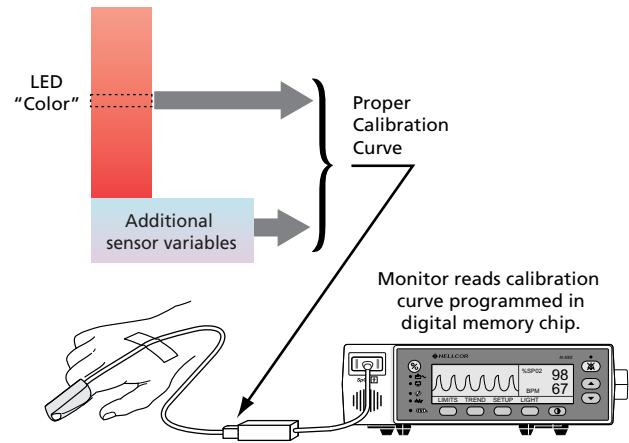


Figure 5

A small digital memory chip resides in every *OxiMax* sensor. The chip is programmed with the full calibration information for that sensor, along with any other sensor-specific data the oximeter can use for enhanced performance.

Sensor Calibration and the New Versatility

Sensor calibration requirements still exist with the *OxiMax* platform; however, instead of relying on a limited number of preprogrammed curves within the monitor, the *OxiMax* system relocates the sensor's individual calibration curve into the sensor itself. In this new design, every *OxiMax* sensor is digitally programmed with the specific coefficients that define its proper calibration curve.

As before, Nellcor fully characterizes the optical properties of each sensor's emitter assembly, though now additional factors are considered to better account for the spectral properties that affect accuracy. The appropriate calibration coefficients for each sensor are determined using a proprietary method and are then stored directly within the digital memory chip.

The past limitations of monitor-based calibration simply vanish. Nellcor can now store within the chip virtually any calibration curve needed, whether for today's sensor designs or for those to be created in the future. Because new curves can be developed as needed, Nellcor can design new sensors with improved performance. Nellcor can also utilize optical components previously incompatible with its earlier oximeters.

Though pulse oximeter monitors could conceivably be reprogrammed with additional curves, the process is unwieldy and cumbersome, particularly with large numbers of installed standalone and multiparameter monitors in hospitals around the nation and throughout the world. With the

OxiMax platform, accommodating updated or entirely new sensor calibration becomes a seamless process for the hospital staff: It occurs automatically when the sensor is plugged in. Implementing upgrades through sensors, rather than monitors, is more cost effective for the customer.

The memory chip also provides room for additional sensor-specific operating parameters to be stored within the sensor. For example, the model name of the sensor being used is stored, and model-specific troubleshooting tips are provided to the bedside caregiver for optimal sensor application, as described in the Sensor Messages section.

The strength of the *OxiMax* platform resides in the flexibility provided by the sensor's digital memory chip. Not only have new features been introduced with the first *OxiMax* products, but also future enhancements can be accommodated because Nellcor designed the *OxiMax* platform to be extensible. The system architecture gives design engineers complete flexibility for expanding the clinical utility of the system.

Summary of *OxiMax* digital memory chip benefits:

- Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor.
- Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages.
- Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report.

The *OxiMax* Pulse Oximetry System

The *OxiMax* system includes a new line of pulse oximetry monitors and *OxiMax*-enabled OEM modules. These products contain Nellcor's advanced digital signal processing technology. This technology enables the monitor to deliver accurate SpO₂ and pulse rate readings even when confronted with challenging conditions, such as patient motion combined with low pulse perfusion. The system also includes a complete line of single-patient-use and reusable *OxiMax* sensors.

The new *OxiMax* sensors, with the exception of the *MAX-FAST*™ Forehead Sensor and *SoftCare*™ Nonadhesive Sensors, can be used with earlier Nellcor technology. However, some of the *OxiMax*-specific features will not be accessible. Such backward-compatible *OxiMax* sensor models are identified by their purple connector plugs.

The *MAX-FAST* and *SoftCare* sensors were the first sensors to be engineered as part of the *OxiMax* system. Because of unique operating characteristics and calibration curves outside those established in legacy Nellcor systems, these sensors operate only with *OxiMax* monitors. A white connector plug identifies these sensors as exclusively for use with *OxiMax* technology.

***MAX-FAST* Forehead Sensor Delivers a Low Perfusion Solution**

When patients have poor pulse perfusion, arterial blood traveling from the heart reaches the head sooner than it reaches distal sites such as the fingers. This concept inspired the creation of the Nellcor *MAX-FAST* Forehead Sensor. Designed for use on the patient's forehead, the *MAX-FAST* sensor responds to changes in arterial oxygen saturation typically one to two minutes sooner than digit sensors for patients with weak pulses.¹

In addition to alerting clinicians earlier to hypoxic events, the *MAX-FAST* sensor is often able to provide SpO₂ readings when conventional monitors with digit sensors fail. Because forehead circulation is fed by the supraorbital artery, this area is not prone to vasoconstriction during low perfusion. Thus, when digit sensors fail to detect adequate pulsatile signals, the *MAX-FAST* sensor provides an effective monitoring option.

The new versatility of the *OxiMax* platform enabled Nellcor to design a forehead sensor that is more accurate than other sensors designed for head sites (forehead, ear or nose). The *MAX-FAST* sensor has an accuracy level of $\pm 2\%$, which is comparable to many digit sensors. No other "head" sensor provides this level of accuracy.

The *MAX-FAST* sensor replaces the Nellcor RS-10 Reflectance Sensor—a forehead sensor based on earlier technology. The bandaging material and adhesive attachment of the *MAX-FAST* sensor have been updated, and it has a more efficient and spectrally different LED compared with other Nellcor sensors. Because the *MAX-FAST* sensor is calibrated specifically for use on the forehead, its calibration differs from the existing RCAL curve set.

Following is a summary of *MAX-FAST* Forehead Sensor advantages:

- During poor peripheral perfusion, *OxiMax* systems using *MAX-FAST* sensors reflect changes in SpO_2 typically one to two minutes earlier than sensors placed on digits.¹
- The *MAX-FAST* sensor can often obtain SpO_2 readings when digit sensors fail to detect pulsatile signals.
- The forehead site is less vulnerable to peripheral vasoconstriction and hence maintains signals longer than digit sensors during conditions of poor peripheral circulation. Ear sensors also show degraded signal strength during similar monitoring conditions.²
- The forehead sensor site is readily accessible, particularly in the operating room when patients' hands are covered and beyond the reach of the anesthesiologist.
- SpO_2 accuracy is improved over prior head sensor options; *MAX-FAST* accuracy is comparable to adult finger sensors (± 2 saturation points, 1 SD).
- The head is typically a lower motion site than the hands, and thus often offers more reliable readings on moving patients.³
- Opaque sensor optics allow the sensor to tolerate high ambient lighting environments.
- A single *MAX-FAST* sensor can be used for up to two days, with appropriate site inspections and changes.

SoftCare Nonadhesive Sensors Help Protect Fragile Skin

Another *OxiMax* sensor developed to address a specific clinical need is the *SoftCare* Nonadhesive Sensor. The *SoftCare* sensor was designed in response to concerns that applying and removing adhesives can cause skin trauma for neonatal patients with fragile skin. Adhesives can also be a concern for geriatric and burn patients. While most single-patient-use sensors use adhesive tape, the *SoftCare* Nonadhesive Sensor fastens with Velcro® instead. The sensor bandage is made of a soft, pliable foam material that gives it "stiction" to help keep the sensor securely in place.

As with the *MAX-FAST* Forehead Sensor, Nellcor was able to design the *SoftCare* sensor with a high accuracy specification ($\pm 2\%$ on adults, $\pm 3\%$ on neonates) due to the flexibility in selecting calibration curves. *SoftCare* sensors are also designed with high-efficiency LEDs that enhance the sensor's ability to acquire a pulsatile signal, even when challenged with thicker or darkly pigmented skin, or weak pulses.

***OxiMax* Communication Features**

Taking advantage of the digital memory housed within each *OxiMax* sensor, Nellcor was able to develop new pulse oximeter functions that communicate with the caregiver to enhance monitoring effectiveness and patient management. Two of these functions, Sensor Messages and Sensor Event Report, are available in full-featured *OxiMax* monitors, such as the *OxiMax* N-595 Pulse Oximeter.

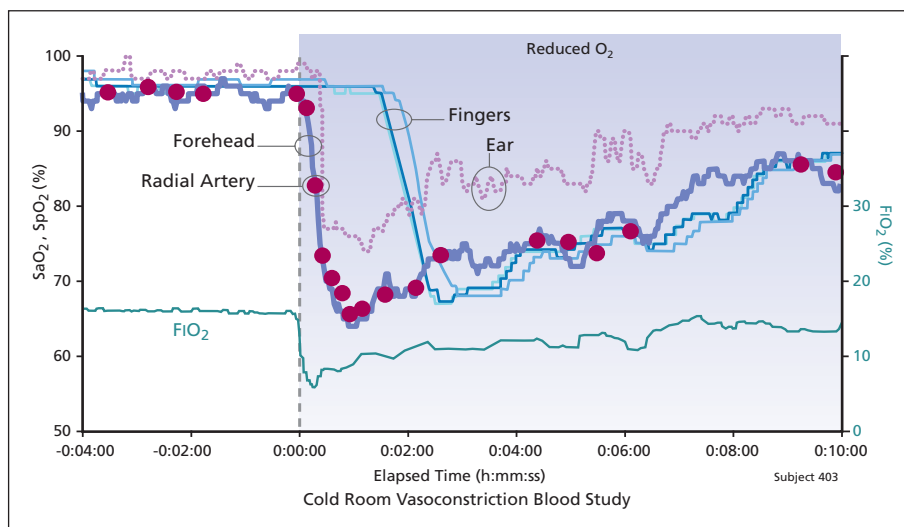


Figure 6
The *MAX-FAST* Forehead Sensor detects changes in SpO_2 faster than finger sensors, and with accuracy that more closely tracks to arterial blood data.

Sensor Messages Function Helps Caregivers With Sensor Application

The Sensor Messages function is a new clinical utility that provides troubleshooting tips to aid clinicians in optimizing sensor application.

The Sensor Messages feature of the *OxiMax* system examines the information available from the sensor, and uses a proprietary algorithm to evaluate parameters programmed into the memory chip of the particular sensor being used and current signal characteristics coming from the patient. If the monitor is unable to post saturation or pulse rate values after the clinician applies and connects the sensor, the Sensor Messages feature displays specific suggestions to improve signal acquisition. (When the sensor is not placed properly, the monitor will display zeroes rather than show inaccurate SpO₂ readings.) Any combination of three conditions may be displayed, along with up to five Action Messages (see Table 1). The Action Messages are tailored to the type of sensor connected to the monitor.

Conditions	Action Messages
•Sensor Off	•Adhesive/ <i>OxiMax</i> Sensor
•Weak Pulse	•Reposition Sensor
•Weak Signal	•Warm Site
•Motion Interference	•Alternate Site
•Excess Infrared Light	•Nasal/Ear Sensor
•Electrical/Light Interference	•Clean Sensor Site (R-15)
•High Pulse Amplitude	•Ear/Forehead Sensor
	•Secure Cable
	•Headband (<i>MAX-FAST</i>)
	•Bandage Assembly
	•Nail Polish
	•Sensor Too Tight
	•Isolate Interference
	•Cover Sensor Site

Table 1

This table shows all the possible conditions and action messages that can be displayed with the Sensor Messages function. Depending on the particular situation and sensor type being used, the monitor will display up to three conditions and up to five action messages. These messages help the clinician address sensor application problems that may be preventing the monitor from posting SpO₂ readings.

For example, the *OxiMax* system can warn clinicians that the sensor may be positioned on an inappropriate site for that type of sensor. Improper sensor placement, such as a digit sensor placed on the forehead, is a common problem with less experienced caregivers. In this situation the caregiver may be inclined to throw away the sensor and try a new one, thinking the sensor was faulty. The Sensor

Messages function helps eliminate this problem by alerting the clinician to move the sensor to a proper site. In short, Sensor Messages helps take the guesswork out of sensor application, which saves clinician time and prevents sensor waste.

Sensor Event Report Aids in Patient Assessment

Full-featured *OxiMax* monitors can record data to, and display previously recorded information from, an *OxiMax* sensor's digital memory chip. Using a feature called Sensor Event Report, alarm events stored in the sensor can easily be accessed and displayed on the monitor. This allows caregivers to quickly assess whether patients have had hypoxic events during transport or in the prior areas of care.**

Consider the following scenario in which an *OxiMax* sensor is applied to a patient. After undergoing major surgery, the patient leaves the operating room and is transferred directly to the ICU. Upon arrival in the ICU the critical care clinicians connect the patient to a monitor containing *OxiMax* pulse oximetry, and they notice the patient's SpO₂ is low. The anesthesiologist reported SpO₂ above 90% when the patient left the OR, so the clinicians wonder what has happened. Using the Sensor Event Report function they can view alarm events stored in the *OxiMax* sensor. The monitor displays the severity and timing of alarm violations that occurred during the transport period. This information helps the clinicians to better plan and manage care for this particular patient.

Conclusion

The *OxiMax* Pulse Oximetry System was designed with the future in mind. As clinicians continually seek better ways to care for and treat their patients, Nellcor wants to keep pace with technology that supports their goals. Nellcor engineers, with their years of experience in designing pulse oximetry systems, developed *OxiMax* technology to gain the versatility needed to make pulse oximetry monitoring as effective as possible. The *OxiMax* platform, with the digital memory chip in the sensor, frees us from the constraints of the past monitor-based sensor calibration scheme, and gives Nellcor the latitude to provide clinicians with new types of sensors and monitoring features.

**Non-*OxiMax* monitors do not have the necessary hardware to write-to or read-from the digital memory chip and therefore cannot create or access Sensor Event Reports. The Sensor Event Report feature can only be accessed with *OxiMax*-enabled monitors that have the necessary display capability.

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EXHIBIT 4

NELLCOR

OPERATOR'S MANUAL

NPB-195 Pulse Oximeter



MALLINCKRODT

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

To contact Mallinckrodt's representative: In the United States, call 1.800.635.5267 or 314.654.2000; outside of the United States, call your local Mallinckrodt representative.

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SAFETY INFORMATION

General Safety Information

GENERAL SAFETY INFORMATION

This section contains important safety information related to general use of the NPB-195 pulse oximeter. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Read all text surrounding all precautionary information.

Important! Before use, carefully read this manual, accessory directions for use, all precautionary information in boldface type, and specifications.

WARNING: Explosion hazard. Do not use the NPB-195 pulse oximeter in the presence of flammable anesthetics or gases.

WARNING: The NPB-195 is a prescription device and is to be operated by qualified personnel only.

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

Caution: When connecting the NPB-195 to any instrument, verify proper operation before clinical use. Both the NPB-195 and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC Standard 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port (NPB-195 data port connector) configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1 and

Safety Information

**the electromagnetic compatibility system standard IEC
Standard 601-1-2.**

To ensure accurate readings, consider the environmental conditions that are present and the condition of the patient. See the appropriate sections of the manual for specific safety information related to these conditions.

INTRODUCTION

Intended Use

General Operating Principles and Conditions

INTENDED USE

The purpose and function of the Nellcor NPB-195 pulse oximeter are to continuously and noninvasively measure functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). It is also used to display plethysmographic waveforms. Refer to *Appendix B: Principles of Operation* for a more detailed discussion of oximetry.

The monitor is intended for use on adult, pediatric, and neonatal patients in all hospital areas, hospital-type facilities, and home environments. It may be used during intra-hospital transport when powered by its internal battery.

<p>WARNING: The NPB-195 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.</p>

GENERAL OPERATING PRINCIPLES AND CONDITIONS

The NPB-195 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO₂).

Note: For an explanation of functional versus fractional saturation, refer to *Appendix B, Principles of Operation*.

Because a measurement of SpO₂ is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Introduction

Specific information about ambient environmental conditions, sensor application, and patient conditions is contained throughout this manual.

CONTROLS, INDICATORS, AND SYMBOLS

Displays, Controls, Indicators, and Connectors
NPB-195 Symbols
Description of Controls
Description of Displays and Visual Indicators
Description of Audible Indicators

DISPLAYS, CONTROLS, INDICATORS, AND CONNECTORS

Figures 1 and 2 show the front and rear views of the NPB-195 and identify displays, controls, and connectors.

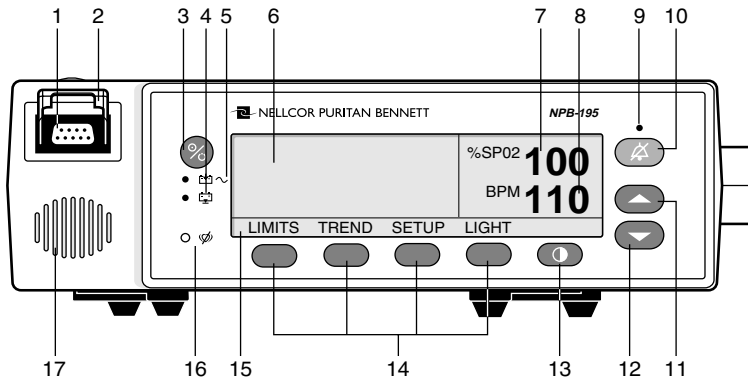


Figure 1: NPB-195 Front Panel Display (Pleth View)

- | | |
|--------------------------------|---------------------------|
| 1 SpO ₂ Sensor Port | 10 Alarm Silence Button |
| 2 Sensor Lock | 11 Adjust Up Button |
| 3 Power On/Off Button | 12 Adjust Down Button |
| 4 Low Battery Indicator | 13 Contrast Button |
| 5 AC Power Indicator | 14 Softkeys |
| 6 Waveform Display | 15 Menu Bar |
| 7 %SpO ₂ Display | 16 Pulse Search Indicator |
| 8 Pulse Rate Display | 17 Speaker |
| 9 Alarm Silence Indicator | |

Controls, Indicators, and Symbols

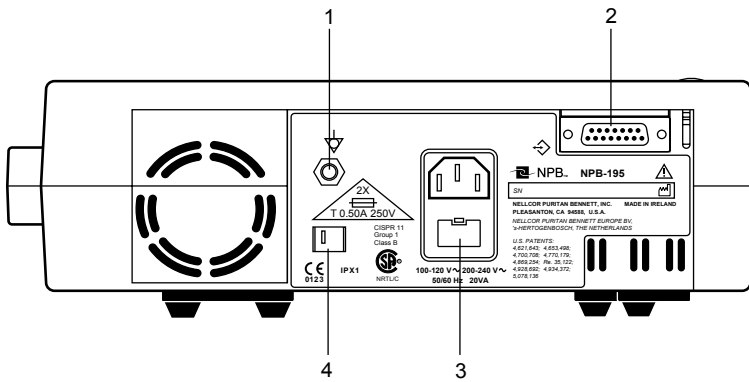


Figure 2: NPB-195 Rear Panel

- 1 Equipotential (ground) Terminal
- 2 Data Port Connector
- 3 Fuse Receptacle
- 4 Supply Voltage Selector Switch

NPB-195 SYMBOLS



See Instructions for Use



Fuse Replacement



Equipotential Terminal



Type BF Applied Part - Not defibrillator proof



Date of Manufacture



Data Interface

Controls, Indicators, and Symbols

DESCRIPTION OF CONTROLS

Function Buttons



The Power On/Off Button. Used to turn the NPB-195 monitor on or off.



The Alarm Silence Button. Used to silence current alarms for the alarm silence duration period. When an alarm has been silenced, pressing the button again reactivates, or “unsilences” the alarm. It is also used to view and adjust alarm silence duration and alarm volume.



The Adjust Up Button. Used to increase alarm limit values, alarm silence duration, pulse beep volume, alarm volume, contrast, date and time values, data port baud rate, and to move the cursor to the right (in the trend view).



The Adjust Down Button. Used to decrease alarm limit values, alarm silence duration, pulse beep volume, alarm volume, contrast, date and time values, data port baud rate, and to move the cursor to the left (in the trend view).



The Contrast Button. Used in conjunction with the Adjust Up/Down Buttons to lighten or darken the display screen.



The softkey buttons have multiple uses depending on the label displayed above the button.

DESCRIPTION OF DISPLAYS AND VISUAL INDICATORS

%SP02 **100**

The %SpO2 Display. Shows the hemoglobin oxygen saturation level. It flashes during loss-of-pulse alarms and when SpO2 is outside of the alarm limits. During Pulse Search, the display will alternate between dashed lines and the last oxygen saturation measurement.

Controls, Indicators, and Symbols



The Pulse Amplitude Indicator (blip bar). Indicates pulse beat and shows the relative pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse. This indicator is available only in the magnified (blip) view.

BPM **86**

The digital Pulse Rate Display. Shows the pulse rate in beats per minute. It flashes during loss-of-pulse alarms and when the pulse rate is outside of the alarm limits. During Pulse Search, the display will alternate between dashed lines and the last pulse rate measurement.



The AC Power Indicator. Lights continuously when the NPB-195 is connected to AC power. It also indicates that the battery is charging. It is off when the monitor is being powered by its internal battery.



The Low Battery Indicator. Lights continuously to indicate that 15 or fewer minutes of battery capacity remains.



The Alarm Silence Indicator. Lights continuously when an audible alarm has been silenced. It flashes when the alarm silence duration has been set to OFF and the Alarm Silence Button is pressed.



The Pulse Search Indicator. Lights continuously prior to initial acquisition of a pulse signal, and during Pulse Search. It flashes during a loss-of-pulse signal.

DESCRIPTION OF AUDIBLE INDICATORS

Following are descriptions of NPB-195 audible indicators.

Power-On Self-Test Pass	A 1-second tone indicating that the NPB-195 has been turned on and successfully completed the power-on self-test
Valid Button Press	A short, medium-pitched tone indicating that an appropriate button has been pressed

Controls, Indicators, and Symbols

Invalid Button Press	A short, low-pitched tone indicating that a button has been pressed that is not appropriate for the current state of the monitor
High Priority Alarm	A high-pitched, fast-pulsing tone indicating loss of pulse
Medium Priority Alarm	A medium-pitched, pulsing tone indicating an SpO2 or pulse rate limit violation
Low Priority Alarm	A low-pitched, slow-pulsing tone indicating a sensor disconnect, low battery, or monitor failure
Alarm Silence Reminder	Three beeps that sound at least every 3 minutes when alarms are silenced with the alarm silence duration set to OFF
Pulse Beep	A single beep sounds for each detected pulse
Volume Setting Tone	A continuous tone that is used to adjust the alarm volume
Confirmation Tone	Three beeps sound to indicate that default settings have been saved or reset to factory defaults or trend data has been deleted

SETUP

Unpacking and Inspection
Performance Verification
List of Components
Monitor Setup
Language Selection

UNPACKING AND INSPECTION

Notify the carrier if the shipping carton is damaged. Unpack the NPB-195 and components. If anything is missing or damaged, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

PERFORMANCE VERIFICATION

Before using the NPB-195 for the first time in a clinical setting, you must verify that the monitor is working properly as described in the Power-on Self-test paragraph of the *Start-up and Use* section. If the monitor does not operate properly, refer to the *Troubleshooting* section. If you cannot resolve the problem, contact qualified service personnel or your local Mallinckrodt representative.

LIST OF COMPONENTS

- 1 Nellcor NPB-195 pulse oximeter
- 1 Hospital-grade power cord
- 1 Operator's manual
- 1 Nellcor sensor or assortment pack
- 1 Sensor extension cable, model EC-8
- 2 Fuses, 0.5 Amps, 250 Volts

Setup

Optional Accessories

The following items are available from Mallinckrodt for use with this monitor:

- Wall mount plate
- Tilt-stand supports

MONITOR SETUP

General Warnings

WARNING: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: Disconnect the NPB-195 and Nellcor sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NPB-195 may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.

WARNING: To ensure accurate performance and prevent device failure, do not subject the NPB-195 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Do not use an NPB-195 monitor, sensor, cable, or connector that appears to be damaged.

WARNING: The NPB-195 is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter.

Connecting the NPB-195

The NPB-195 operates on AC power when the hospital-grade power cord is connected to both the monitor and an AC power source (wall outlet).

The supply voltage selector switch allows connection of the monitor to AC power ranging from 100 VAC to 240 VAC. The switch has two positions: one for 100-120 VAC (“115”), and one for 200-240 VAC (“230”). *Ensure that the supply voltage selector switch on the rear panel is set to the proper voltage.*

Operating on a discharged battery

The NPB-195 will not operate when its internal battery is discharged, even when the monitor is connected to AC power. Instead, the error code “EEE 04” will be displayed. This feature prevents the accidental use of the monitor with a dead battery. The monitor is only capable of indicating a loss of AC power if its internal battery is functional.

The battery may discharge during prolonged storage or shipment. If the monitor has been in storage for more than 2 months it is important to plug the monitor into an AC outlet and allow the battery to charge for approximately 30 minutes before attempting to operate the instrument on AC power.

To charge a low battery, connect the monitor to AC power. A full charge of a completely discharged battery takes 14 hours while turned off, or 18 hours during regular use.

If AC power is not available, you may operate the NPB-195 on battery power for a limited amount of time. In that case, skip Steps 2, 3, and 4 below.

1. Place the NPB-195 on a flat surface near the patient. With the optional wall mount plate available from Mallinckrodt, the monitor may be attached to a GCX Poly-mount bracket.
2. Plug the female connector end of the power cord into the rear of the monitor. Use only the hospital-grade power cord provided by Mallinckrodt.
3. Plug the male connector end of the power cord into a properly grounded AC outlet.

Setup

4. Verify that the AC Power Indicator is lit. If it is not, ensure that the supply voltage selector switch matches your AC voltage source. If the indicator still does not light, contact qualified service personnel, your local Mallinckrodt representative, or Mallinckrodt's Technical Services Department.

WARNING: In the USA, do not connect the monitor to an electrical outlet controlled by a wall switch because the monitor may be accidentally turned off.

5. Select a Nellcor sensor appropriate for the patient to be monitored (see the *Sensors and Accessories* section of this manual for sensor selection information). If needed, an EC-4 or EC-8 sensor extension cable may be used.
6. Plug the sensor into the sensor port located on the front of the NPB-195.
7. Once the sensor is properly plugged into the monitor, lock the sensor in place by lowering the plastic sensor lock over the sensor connector. Press the sensor lock until it clicks into place.

LANGUAGE SELECTION

The languages available for display on the screen are English, French, German, Dutch, Portuguese, Spanish, and Italian. The NPB-195 is shipped with the factory default English language displayed.

To select the appropriate language after the unit is powered on, press the SETUP softkey, then the NEXT softkey, then the LANG softkey. Use the Adjust Up and Adjust Down Buttons to select the desired language. Press the EXIT button to return to the main menu.

Service personnel may set the appropriate language as the power-on default using the procedure described in the NPB-195 service manual.

SENSORS AND ACCESSORIES

Selecting a Sensor
Biocompatibility Testing
Performance Considerations
Optional Accessories

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

WARNING: Use only Nellcor sensors and sensor cables with this monitor. Other sensors or sensor cables may cause improper NPB-195 performance.

WARNING: Use only one extension cable to increase the length of the sensor. Use of more than one extension cable may have an adverse effect on performance. Do not attach to the sensor port cables that are intended for computer use.

WARNING: Do not use the NPB-195 or Nellcor sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NPB-195 may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Sensors and Accessories**Table 1: Nellcor Sensors**

Sensor	Model	Patient Size
<i>Oxisensor</i> ® II oxygen transducer (sterile, single-use only)	N-25/N-25LF I-20/I-20LF D-20 D-25/D-25L R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
<i>Oxiband</i> ® oxygen transducer (reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
<i>Durasensor</i> ® oxygen transducer (reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (reusable/nonsterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer (reusable/nonsterile)	D-YS	>1 kg
For use with Dura-Y sensor:		
Ear clip (reusable, nonsterile)	D-YSE	>30 kg
Pedi-Check™ pediatric spot-check clip (reusable, nonsterile)	D-YSPD	3-40 kg
OxiCliq® oxygen transducers (sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

BIOCOMPATIBILITY TESTING

Biocompatibility testing has been conducted on Nellcor sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

PERFORMANCE CONSIDERATIONS

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Sensors and Accessories

Inaccurate measurements can be caused by:

- incorrect application of the sensor
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- excessive patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- defibrillation

Other physiological conditions or medical procedures that may interfere with the monitor's measurements include significant levels of dysfunctional hemoglobin, low perfusion, and dark pigment.

Loss-of-pulse signal can occur for the following reasons:

- the sensor is too tight
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

<p>WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO₂ sensor. Inspect the sensor site as directed in the sensor directions for use.</p>
--

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO₂ sensor. To prevent interference

Sensors and Accessories

from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

Note: Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- verify that the sensor is properly and securely applied
- move the sensor to a less active site
- use an adhesive sensor that tolerates some patient motion
- use a new sensor with fresh adhesive backing

If poor perfusion affects performance, consider using the *Oxisensor* R-15 sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This sensor may obtain measurements when peripheral perfusion is relatively poor. For low peripheral perfusion, consider using the Nellcor RS-10 sensor, which is applied to the forehead or temple. These are sites that may be spared during peripheral vasoconstriction.

OPTIONAL ACCESSORIES

The wall mount plate and tilt-stand supports are available by contacting Mallinckrodt Technical Services or your local Mallinckrodt representative.

Wall Mount Plate

An optional wall mount plate fits standard, commercially available GCX Poly-mount brackets, and is used to securely mount the monitor to a wall.

The plate attaches to the bottom of the NPB-195 monitor as shown in Figure 3.

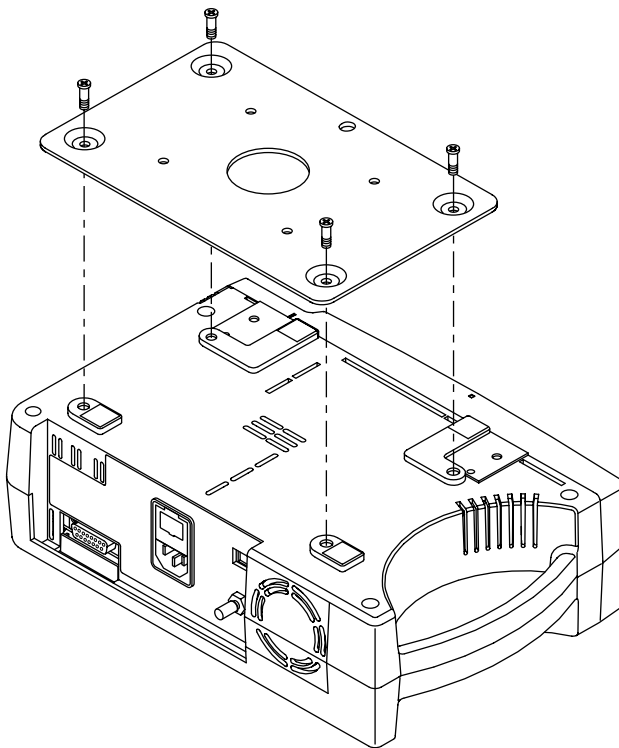


Figure 3: Attaching the Mounting Plate

Sensors and Accessories

Tilt-Stand Supports

A pair of tilt-stand supports provide the option of tilting the front of the monitor upward in order to view the display at an angle. When not in use, the supports can be folded flat against the bottom of the monitor.

The supports are attached to the NPB-195 as shown in Figure 4.

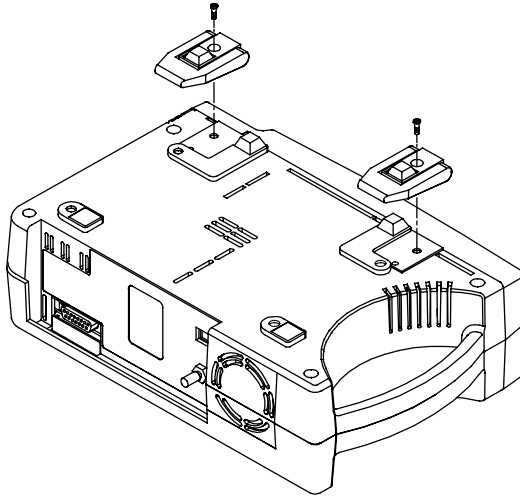


Figure 4: Attaching the Tilt-Stand Supports

START-UP AND USE

Basic Operation
Alarms
Adjustable Settings
Menu
Battery Operation
Disposal of Device Components

BASIC OPERATION

WARNING: The NPB-195 is a prescription device and is to be operated by qualified personnel only.

WARNING: Do not lift the monitor by the sensor cable or power cord because the cable or cord could disconnect from the monitor, causing the monitor to drop on the patient.

WARNING: The NPB-195 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

Important! Prior to using the NPB-195, carefully read this manual, accessory directions for use, all precautionary information in boldface type, and all specifications.

Before using the NPB-195 in a clinical setting, you must verify that the monitor is working properly and is safe to use. Proper working condition can be verified by successful completion of the power-on self-test described in the following steps, and by following instructions contained in the “Monitoring Mode” paragraph of this section.

Ensure that the supply voltage selector switch on the rear panel is set to the proper voltage.

Start-Up and Use

Power-On Self-Test (POST)

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

1. Plug an appropriate Nellcor sensor firmly into the sensor port. Secure by pulling the sensor lock over the sensor until it locks into place. Apply the sensor to the patient as described in the sensor directions for use. If needed, use a Nellcor sensor extension cable, model EC-4 or EC-8.
2. Turn on the NPB-195 by pressing the Power On/Off Button. The monitor automatically starts a power-on self-test (POST), which tests its circuitry.
3. During the POST, the entire display lights and then the Nellcor Puritan Bennett logo with model number and software version are displayed for approximately 3 seconds. All indicator lights illuminate briefly.

Caution: If any indicator or display element does not light, do not use the monitor. Instead, contact qualified service personnel, your local Mallinckrodt representative, or Mallinckrodt's Technical Services Department.

4. If the NPB-195 detects an internal problem during POST, an error code or error message may be displayed and a low priority alarm will sound. Depending on the reason for the failure, the screen may be blank or the low priority alarm may not sound. Refer to the *Troubleshooting* section for a list of correctable error messages.
5. Upon successful completion of the POST, the NPB-195 sounds a 1-second tone indicating that the monitor has passed the test.

WARNING: If you do not hear the POST pass tone, do not use the monitor.

6. If a sensor is connected to the monitor and the patient, the Pulse Search Indicator lights and the NPB-195 displays zeroes in the %SpO₂ and Pulse Rate Displays while it searches for a valid pulse. If a sensor is not attached to the monitor, dashes are displayed and the Pulse Search Indicator is not lit.

When a valid pulse is detected, the NPB-195 enters Monitoring Mode and a display similar to the one indicated in either Figure 5 or Figure 6 is displayed.

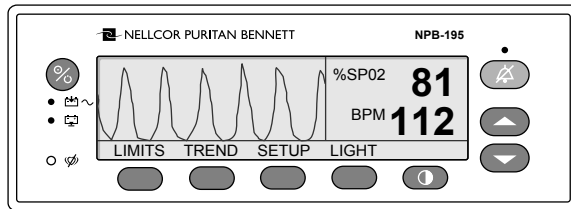


Figure 5: Monitoring Mode Display - Pleth View

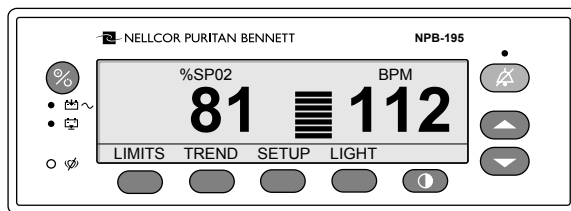


Figure 6: Monitoring Mode Display - Magnified View

Contrast

To adjust the screen contrast, press and hold the Contrast Button. Press the Adjust Up or Adjust Down Button to increase or decrease the contrast. Continue to press and hold the buttons to adjust the value at a faster rate.

Start-Up and Use

Monitoring Mode

In Monitoring Mode - Pleth View (Figure 5), the NPB-195 displays SpO₂ readings, pulse rate readings, and a pleth waveform. In the Monitoring Mode - Magnified (blip) View (Figure 6), the Pulse Amplitude Indicator and a larger %SpO₂ and pulse rate reading are displayed. The pleth waveform is not displayed. How to select one of the two views by using the softkeys will be discussed later in this section.

%SpO₂ is displayed for values between 0% and 100%. Pulse rates are displayed for values from 20 to 250 beats per minute and zero beats per minute. Pulse rates below 20 (except zero) will be displayed as 20, and pulse rates above 250 will be displayed as 250. A pulse rate of zero is used to indicate that the monitor is not monitoring a pulse.

A variable-pitch beep sounds once for each pulse, and the Pulse Amplitude Indicator (in the Magnified View) visually displays relative pulse strength at the sensor site. The pitch of the beep decreases as %SpO₂ decreases.

Note: Verify that indicators, display information, and audible sounds including alarms are operational, indicating that the monitor is functioning. Each valid button push should generate an appropriate audible or visual action. Observe movement of the Pulse Amplitude Indicator or pleth waveform, and listen for pulse beeps to verify that measurements are being made.

If any action does not seem appropriate, do not use the monitor. Instead, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

In Monitoring Mode, if the acquired pulse is lost, the monitor enters Pulse Search Mode.

Pulse Search

If the acquired pulse is lost during monitoring, the NPB-195 enters Pulse Search. During Pulse Search, the monitor attempts to detect a pulse from which to take a measurement.

Note: Pulse Search is a normal function of the monitor, and entering this mode does not *necessarily* mean that the patient has no pulse.

At Initial Power-Up (*Sensor Attached to Monitor*)

Immediately after POST is completed and the NPB-195 displays its software version number, the monitor enters Pulse Search Mode and the Pulse Search Indicator lights. If an attached sensor is not connected to a patient, the display reads zeroes and the monitor remains in the Pulse Search Mode. If the sensor is connected to the patient, the NPB-195 enters the Monitoring Mode when a pulse is detected.

At Initial Power-Up (*No Sensor Attached to Monitor*)

Immediately after POST is completed and the NPB-195 displays its software version number, the monitor displays dashes. It does not enter the Pulse Search Mode.

After Taking Measurements

If a pulse was previously acquired and then lost for 4 seconds, the NPB-195 enters Pulse Search, and the Pulse Search indicator lights. The display flashes the last detected readings while the monitor searches for a valid pulse. When the monitor has been in the Pulse Search Mode for approximately 6 seconds, it displays flashing zeroes and a high priority alarm sounds.

When a valid pulse is detected, the NPB-195 exits the Pulse Search Mode and displays the current readings. The Pulse Search indicator goes out.

Automatic Shutdown

When all of the following conditions are present for 15 minutes, the NPB-195 will automatically shutdown:

- Running on battery power
- No buttons have been pressed
- No pulse has been detected (for example, when no patient is connected to the sensor or the sensor is disconnected)

Start-Up and Use

- No alarms are present (other than low battery or a non-correctable error)

ALARMS

Description of Alarms

The NPB-195 has three levels of audible alarms.

1. *High-priority alarm:* Indicated by a fast-rate, high-pitched, pulsing tone. A high-priority alarm sounds after loss-of-pulse is detected.

During a loss-of-pulse alarm, the %SpO₂ and Pulse Rate Displays are set to zero and flash. The Pulse Search Indicator also flashes.

2. *Medium-priority alarm:* Indicated by a medium-rate, medium-pitched, pulsing tone. A medium-priority alarm sounds when any measured patient parameter moves outside the set alarm limits.

During a medium-priority alarm, the display flashes with the patient parameter that violated the limit (%SpO₂ or Pulse Rate).

3. *Low-priority alarm:* Indicated by a slow, low-pitched, pulsing tone. A low-priority alarm sounds during the following conditions:

- when an SpO₂ cable has disconnected
- monitor failure
- low battery (while operating on battery power)

When operating on DC power, during a low battery condition, the Low Battery Indicator illuminates and the alarm tone sounds immediately, even if the alarms are silenced or set to OFF.

ADJUSTABLE SETTINGS

The following adjustments can be made using the Adjust Up/Down and Alarm Silence Buttons.

- Pulse beep volume
- Alarm volume
- Alarm silence duration
- Disabling audible alarms

Pulse Beep Volume

To adjust the pulse beep volume during normal monitoring, press and hold the Adjust Up or Adjust Down Button to change the setting. Pressing and holding the Adjust Down Button will cause the volume to decrease until it is no longer heard.

Alarm Volume

To *view* the current volume of the audible alarm, press and hold the Alarm Silence Button for more than 3 seconds. The current volume level is indicated in the Pulse Rate Display as a value from 1 (lowest) to 10 (highest). A tone at the displayed level sounds.

To *adjust* the volume, press and hold the Alarm Silence Button for more than 3 seconds, then press the Adjust Up or Adjust Down Button to change the setting. The volume cannot be set to zero.

Alarm Silence Duration

Alarms can be silenced for a preset period called the *audible alarm silence duration*. To view the current setting, press and hold the Alarm Silence Button for less than 3 seconds. To adjust the setting, press and hold the Alarm Silence Button (for less than 3 seconds) and use the Adjust Up or Adjust Down Buttons to increase or decrease the value. Possible values are 30, 60, 90, or 120 seconds, or OFF. (The OFF selection is discussed later in this section.)

The audible alarm silence duration begins when the Alarm Silence Button is pressed (for less than 3 seconds) and released. (If the

Start-Up and Use

button is pressed for more than 3 seconds or the duration is changed, the Alarm Silence Button must be pressed again to start the alarm silence duration.)

Subsequently, if any alarm condition (other than a low battery alarm) occurs while the alarm is silenced, the alarm will not sound until the alarm silence duration is ended. Operating on battery power during a low battery alarm condition will cause an alarm to sound, even if the duration time has not elapsed.

If the Alarm Silence Button is pressed during the alarm silence duration, the alarm silence duration is ended and the audible alarms are re-enabled.

Visual indications of an alarm condition cannot be turned off. For example, if the %SpO₂ upper alarm limit is exceeded, the alarm can be silenced for the alarm silence duration, but the %SpO₂ value will continue to flash.

If the alarm condition is still present when the alarm silence duration has elapsed, the alarm will sound.

<p>WARNING: Do not silence an audible alarm or decrease its volume if patient safety could be compromised.</p>

Disabling Audible Alarms

Setting the alarm silence duration to OFF means that no audible alarms will be produced by the monitor.

To set the alarm silence duration to OFF, press and hold the Alarm Silence Button for less than 3 seconds and use the Adjust Up Button to increase the current setting until “OFF” is displayed. The next time the Alarm Silence Button is pressed, the Alarm Silence Indicator flashes, indicating that audible alarms have been disabled. If the Alarm Silence Button is pressed again, the Alarm Silence Indicator stops flashing.

Visual indications of an alarm condition are not affected by disabling the audible alarms.

The ability to set the alarm silence duration to OFF can be enabled or disabled by qualified service personnel as described in the

service manual. The factory default is that the capability of setting the alarm silence duration to OFF is enabled.

Alarm Silence Reminder

The alarm silence reminder (three beeps) will sound at least every 3 minutes while the alarm silence duration is set to OFF and the Alarm Silence Indicator is flashing.

Service personnel may disable the alarm silence reminder by using the procedures described in the service manual. The factory default is that the reminder is enabled.

MENU

Menu Structure

The four softkeys on the front panel are used to view or adjust the following NPB-195 settings or functions:

- %SpO₂ and pulse rate alarm limits
- Pleth or magnified view
- Time and date settings
- Data port baud rate settings
- Trend data viewed (%SpO₂, pulse, or both)
- “Zoom” factor of trend data
- Graph of trend data (histogram)
- Delete all trend data
- Print trends
- Language displayed on screen or data port

Menu items are selected by pressing and releasing the corresponding softkey directly below the item. Refer to Figure 7 to access menu items.

Note: If, after accessing a submenu, no buttons are pressed for 10 seconds, the display will timeout and return to the

Start-Up and Use

main menu. Exceptions to this are the clock and trend menus, which will timeout in 5 minutes.

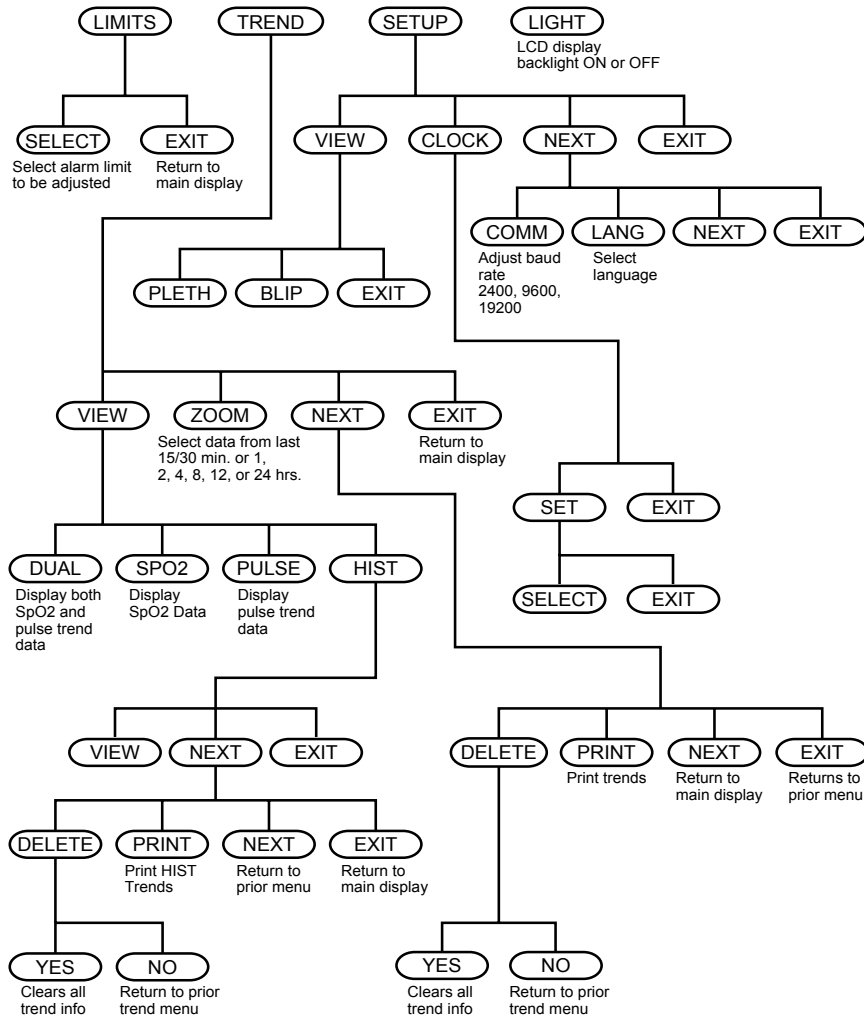


Figure 7: Menu Items

A description of each menu item is included in the following paragraphs.

LIMITS

WARNING: Each time the monitor is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Overview

When the NPB-195 is first turned on, alarm limits are set to their power-on default values. Power-on default alarm limits can be changed by qualified service personnel, using the instructions described in the NPB-195 service manual.

You can temporarily change alarm limits from their power-on default values if necessary, as described below. Changes you make will remain in effect until you change them again, or until you turn off the NPB-195.

Viewing Current Alarm Limits

To view the current alarm limit values from the main menu, press the LIMITS softkey. The current upper and lower alarm limits for %SpO₂ and pulse rate are displayed.

Changing Alarm Limits

Use the SELECT softkey to select the parameter whose value you want to change. Use the Adjust Up/Down Buttons to change the settings. The setting takes effect immediately and remains in effect when the alarm setting menu is exited.

Alarm Limits Changed Indicator

If alarm limits are changed from the NPB-195's power-on defaults, a decimal point appears after the displayed value and in the %SpO₂ and Pulse Rate Display as shown in Figure 8. The decimal point remains on the display until the NPB-195 is turned off or the limit is returned to its default value.

Start-Up and Use

ALARM LIMITS			%SP02	96.
	%SPO2	BPM		
UPPER	100	170	BPM	79
LOWER	80.	40		
SEL			EXIT	

Figure 8: Alarm Limits Selection**TREND**

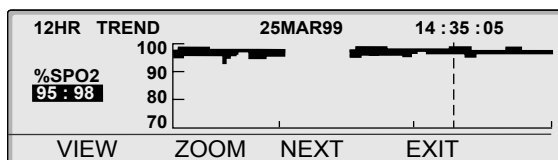
The NPB-195 can graphically display trends for SpO₂, pulse rate, or both for up to the last 24 hours. Trend data is stored at 5-second intervals. When the TREND softkey is pressed, “READING TRENDS . . .” is displayed at the bottom of the screen, indicating that the monitor is collecting the trend data.

The amount of trend data displayed on the screen is determined using the ZOOM softkey. Settings available are 15 or 30 minutes, and 1, 2, 4, 8, 12, and 24 hours. All data is displayed in a graph format.

When the trends are displayed, the most recent readings are on the right side of the graph. The graph indicates the highest and lowest parameter values during the period of time represented by the width of the cursor (vertical dotted line).

%SpO₂ readings below 70 are not displayed. Also, pulse rate readings below 5 bpm and above 200 bpm are not displayed.

The highest/lowest values of the parameter at the cursor are indicated on the left side of the screen (“95” and “98” in Figure 9). These values are *not* the current patient readings but represent the highest and lowest trend values at the cursor.

**Figure 9: SpO₂ Trend**

Periods of time when no measurements were acquired are indicated by blank spaces in the graph as shown in Figure 9.

The number of trend hours or minutes currently displayed on the screen is indicated in the upper left corner. The location of the cursor is indicated by the date and time on the top middle and right of the screen.

The cursor is moved right or left by using the Adjust Up/Down Buttons. Each press of the button causes the cursor to move a certain period of time depending on the trend scale, as indicated in Table 2.

Table 2: Trend Scale

Trend Scale	Amount of Time Represented by One Press of the Adjust Up/Down Buttons
15 minutes	5 seconds
30 minutes	10 seconds
1 hour	20 seconds
2 hours	40 seconds
4 hours	1 minute, 20 seconds
8 hours	2 minutes, 40 seconds
12 hours	4 minutes
24 hours	8 minutes

Scrolling past the limits of the right or left edges of the screen causes the viewing area to jump, relocating the cursor to the middle of the screen if enough trend data is available.

For example, suppose the time represented by the right-hand edge of the screen in Figure 9 is 14:54:05. Scrolling one time period to the right (4 minutes) results in the cursor relocating to the center of the screen at the time period 14:58:05, with 6 hours of data on both sides of the cursor. If no data was available to the right of the screen, an invalid tone would sound. If only 3 hours of data was to the right of the screen, the cursor would relocate to approximately $\frac{3}{4}$ of the way to the right of the screen, at the time period 14:58:05.

Note: The screen will return to the monitoring mode if an alarm sounds, the Alarm Silence Button is pressed or a trend or histogram has been displayed for 5 minutes with no button presses.

Start-Up and Use

View

Pressing the VIEW softkey allows you to select the %SpO₂ or pulse rate trend or both. You can also select the histogram view as illustrated in Figure 10.

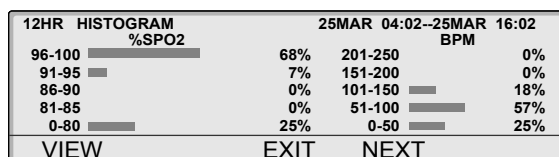


Figure 10: Histogram

Histogram

The histogram graphically illustrates the percentage of time a given range of values has been measured. The period of time covered is given in the upper left corner of the display. Only points with data are included in the histogram.

For example, in Figure 10, the histogram is for the last 12 hours. During those 12 hours, 68% of the %SpO₂ measurements were from 96 to 100, 7% of the measurements were from 91 to 95, and 25% of the measurements were from 0 to 80.

Zoom

Pressing the ZOOM softkey changes the period of time indicated on a trend graph. Selectable times displayed graphically are 24, 12, 8, 4, 2, or 1 hours, and 30 or 15 minutes. The location of the cursor, as indicated by the time in the upper right-hand corner of the screen, remains the same.

The ZOOM softkey is not displayed for the histogram trend view.

Next

The NEXT softkey gives you access to the DELETE and PRINT softkeys.

Delete

Pressing the DELETE softkey presents two options: YES or NO. YES deletes all trend information from the NPB-195 memory and the display. NO returns you to the previous menu.

Print

Pressing the print softkey begins the transmission of data via the data port to a connected PC or serial printer. Refer to Appendix C of this manual for more information concerning the data port.

SETUP

The SETUP softkey allows you to select or view the following settings:

- view displayed on the screen (PLETH or BLIP)
- time and date
- data port baud rate and protocol
- language displayed on the screen

Press the SETUP softkey once to display VIEW and CLOCK. Then press NEXT to display COMM and LANG.

VIEW

The VIEW softkey allows you to select the view displayed on the screen, PLETH or BLIP (magnified). The pleth view displays the pleth waveform. The BLIP view displays the Pulse Amplitude Indicator and larger numerical values for easier viewing.

CLOCK

The CLOCK softkey allows you to set the time and date.

Press the SET softkey to access the SELECT softkey. Use the SELECT softkey to select the item you wish to change. Use the Adjust Up/Down Buttons to adjust the setting. The date is expressed as DD-MMM-YY. For example, March 29, 1999, would be expressed as 29 - MAR - 99.

Press the EXIT button to accept the new settings. Press EXIT again to return to the previous menu.

Start-Up and Use

COMM

The COMM softkey allows you to select the baud rate of the data port.

Press the NEXT softkey to access the COMM softkey. After pressing the COMM softkey, use the Adjust Up/Down Buttons to select a baud rate of 2400, 9600, or 19200. Press Exit to return to the SETUP submenu.

LANG

The LANG softkey allows you to select the language displayed on the screen.

Press the NEXT softkey to access the LANG softkey. After pressing the LANG softkey, use the Adjust Up/Down Buttons to select Dutch, English, French, German, Italian, Portuguese, or Spanish.

If the language is changed and EXIT is pressed, (or a 10-second timeout occurs), the monitor begins displaying data in the selected language.

LIGHT

The LIGHT softkey allows you to turn the backlight on or off.

Default Settings

The NPB-195 is shipped with factory default settings. Authorized technical personnel can change the default settings by using the procedures described in the NPB-195 service manual.

The factory default settings are as follows:

%SpO2 Upper Alarm Limit:	100%
%SpO2 Lower Alarm Limit:	85%
Pulse Rate Upper Alarm Limit:	170 beats per minute
Pulse Rate Lower Alarm Limit:	40 beats per minute
Alarm Volume:	75 dB(A) peak at 1 meter (volume setting of 5)
Alarm Silence Duration:	60 seconds
Alarm Silence Duration OFF Setting:	Enabled

Start-Up and Use

Alarm Silence Reminder:	Enabled
Pulse Beep Volume:	72 dB(A) at 1 meter (volume setting of 4)
Data Port Baud Rate:	9600
Display Format:	Pleth
Trend Display:	%SpO2
Display Contrast:	Midrange
Language:	English

Nurse Call Feature

WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the monitor, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

The nurse call feature of the NPB-195 works in conjunction with the nurse call system of your institution when the monitor sounds an audible alarm. It is accessed through the data port (pin 11, as indicated in Table 5 in Appendix C).

WARNING: The nurse call feature is not functional when the monitor is operated on battery power, or whenever the monitor alarms are silenced.

The nurse call feature is available only when the NPB-195 is operated on AC power and if the monitor has been electronically connected to the hospital's nurse call system.

Qualified service personnel may refer to the NPB-195 service manual for complete connection instructions.

Prior to using the monitor in a clinical setting, test the nurse call feature by creating an alarm condition, then verifying that the hospital's nurse call system is activated.

BATTERY OPERATION

The NPB-195 has an internal battery that may be used to power the monitor during transport or when AC power is not available. A new, fully charged battery will provide at least 6 hours of

Start-Up and Use

monitoring time if there are no audible alarms and the backlight is off.

Note: Whenever the monitor is connected to AC power, the battery is being charged. Therefore, it is recommended that the monitor remain connected to AC power when not in use. This will make available a fully charged battery for use at any time.

Since the monitor cannot operate with a fully discharged battery, before attempting to turn on an NPB-195 whose battery charge has been depleted, first plug the monitor into an AC outlet to allow the battery to charge for a few minutes. The monitor may then be powered on.

To charge a dead battery, connect the monitor to AC power. A full charge takes 14 hours while turned off, or 18 hours during regular use.

When all of the following conditions are present for 15 minutes, the NPB-195 will automatically shutdown:

- Running on battery power
- No buttons have been pressed
- No pulse has been detected (for example, when no patient is connected to the sensor or the sensor is disconnected)
- No alarms are present (other than low battery or a non-correctable error)

Low Battery Indicator

The Low Battery Indicator lights and a low priority alarm begins to sound when approximately 15 minutes of monitoring time is available on the existing battery charge. This alarm is unsilenceable while running on battery power. Connect to AC power to silence the alarm.

Note: If the AC voltage selector switch on the rear panel does not match your AC voltage source, the monitor may run on battery power, even though it is plugged in, which will eventually result in a low priority alarm and a lighted low battery indicator. Ensure that the switch setting matches your AC voltage source.

Start-Up and Use

If the monitor is not connected to AC power within approximately 15 minutes, it will shut down.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter.

If the backlight is turned off during a low battery condition, it cannot be turned back on.

It is recommended that qualified service personnel replace the internal battery every 24 months.

Caution: If the NPB-195 is to be stored for a period of 2 months or longer, notify service personnel to remove the battery from the monitor prior to storage. Recharge the battery when it has not been charged for 2 or more months.

DISPOSAL OF DEVICE COMPONENTS

Caution: Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

TROUBLESHOOTING AND MAINTENANCE

Troubleshooting
EMI Interference
Obtaining Technical Assistance
Returning the NPB-195
Maintenance

TROUBLESHOOTING

WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

Error Codes

When the NPB-195 detects an error condition, it may display the letters "EEE" followed by an error code.

When an error code (other than the ones listed in Table 3) is displayed, turn the instrument off and back on again. If the error code reappears, record it and notify service personnel.

Error messages will be displayed along with the error codes listed in Table 3. If the error codes are encountered, perform the prescribed action as indicated in the table.

Troubleshooting and Maintenance

Table 3: Error Codes and Messages

Error Code	Error Message	Action
4	LOW BATTERY	The battery is discharged to a critically low level. Check to ensure that the voltage selector switch is set to the proper voltage. Turn the monitor off and let it charge for about 10 minutes and then turn the unit back on. If the error code is still present, turn the unit off and let it continue to charge. If the monitor has been charged for 30 minutes and the error code is still present, notify service personnel.
80	DEFAULTS LOST	The current power-on default settings have been lost and returned to factory defaults. Qualified service personnel can use the service manual to restore the desired power-on default settings.
81	SETTINGS LOST	The current settings (for example, alarm limits, alarm and pulse beep volumes, alarm silence duration) have been lost and returned to power-on defaults. Turn the monitor off and back on again. If it is necessary to have settings different from the power-on default settings, turn the monitor off and back on again, and reenter the desired settings.
82	CLOCK SETTING LOST	The date and time settings have been lost. Reenter the date and time.

Other Messages

In addition to the messages listed in Table 3, the following messages may be encountered:

SENSOR DISCONNECTED - The sensor has disconnected from the cable or the cable has disconnected from the monitor. Press the Alarm Silence Button to silence the alarm. Check the connections. If this does not correct the problem, replace the sensor and/or cable.

DISALLOWED ON BATTERY - An attempt to print or download data port information while operating on battery power has been made. Connect to AC power and retry.

Troubleshooting and Maintenance

DISALLOWED ON LOW BATTERY - An attempt to turn on the backlight has been made while in a low battery condition. If the backlight is turned off during a low battery condition, it cannot be turned back on.

READING TRENDS - The monitor is gathering trend information for display.

INVALID SILENCE DURATION - An attempt has been made to set the alarm silence duration power-on default to "OFF". The power-on default cannot be set to "OFF".

INVALID SPO2 LIMIT - An attempt has been made to set either the upper or lower alarm limit power-on default below 80. The power-on default cannot be set below 80.

Suggested Corrective Actions

If you experience a problem while using the NPB-195 and are unable to correct it, contact qualified service personnel or your local Mallinckrodt representative. The NPB-195 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

Following is a list of possible errors and suggestions for correcting them.

1. There is no response to the Power On/Off Button.

- If operating on AC power, ensure that the supply voltage selector switch is set to the proper voltage.
- If operating on AC power, the fuse may be blown. Notify service personnel to check and, if necessary, replace the fuse.
- If operating on battery power, the battery may be missing or discharged. If the battery is discharged, notify service personnel to charge or replace the battery.

2. One or more display elements or indicators do not light during the power-on self-test.

- Do *not* use the NPB-195; contact qualified service personnel or your local Mallinckrodt representative.

Troubleshooting and Maintenance

3. The monitor is operating on battery power, even though it is connected to AC.

- Ensure that the supply voltage selector switch is set to the proper voltage.
- Make sure that the power cord is properly connected to the NPB-195.
- Check to see if power is available to other equipment on the same AC circuit.

4. The Pulse Search Indicator is lit for more than 10 seconds (before any measurements are taken).

- Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and extension cable connections. Test the sensor on someone else. Try another sensor or extension cable.
- Perfusion may be too low for the NPB-195 to track the pulse. Check the patient. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
- Excessive patient motion may be preventing the NPB-195 from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied, and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement, for example, an adhesive sensor.
- The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor, as necessary.
- Excessive environmental motion or electromagnetic interference may be preventing the NPB-195 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

Troubleshooting and Maintenance

5. The Pulse Search Indicator lights *after* successful measurements have been made.

- *Check the patient.*
- Perfusion may be too low for the NPB-195 to track the pulse. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
- Excessive patient motion may be preventing the NPB-195 from tracking the pulse. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement, for example, an adhesive sensor.
- The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor, as necessary.
- Excessive environmental motion or electromagnetic interference may be preventing the NPB-195 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

Other physiological conditions or medical procedures that may interfere with the monitor's measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, and dark pigment.

EMI INTERFERENCE

Caution: This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN60601-1-2:1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

Troubleshooting and Maintenance

The NPB-195 is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.

The NPB-195 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, or to order parts or a service manual, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the NPB-195.

When calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative, you may be asked to tell the representative the serial number and software version of your NPB-195.

The software version number appears in the monitor display each time the monitor successfully completes the power-on self-test. Write the number down and have it available whenever requesting technical assistance.

RETURNING THE NPB-195

Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative for shipping instructions including a Returned Goods Authorization number. It is not necessary to return the sensor. Pack the NPB-195 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the NPB-195 by any shipping method that provides proof of delivery.

MAINTENANCE

Service

The NPB-195 requires no routine service or calibration other than changing the battery at least every 24 months.

If service is necessary, contact qualified service personnel or your local Mallinckrodt representative.

Periodic Safety Checks

It is recommended that the following checks be performed every 24 months.

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.

Performance Verification

If the monitor has been visibly damaged or subjected to mechanical shock (for example, if dropped), qualified service personnel should perform the procedure in the *Performance Verification* section of the service manual.

Cleaning

WARNING: Do not spray, pour, or spill any liquid on the NPB-195, its accessories, connectors, switches, or openings in the chassis.
--

Troubleshooting and Maintenance

To clean the NPB-195, dampen a cloth with a commercial, nonabrasive cleaner or a solution of 70% isopropanol in water, and lightly wipe the surfaces of the monitor. Do not spray or pour liquid on the instrument or accessories.

The NPB-195 may be disinfected using a soft cloth saturated with one of the following solutions:

- 10% chlorine bleach in tap water
- Glutaraldehyde (cidex or equivalent)

Before attempting to clean an SpO₂ sensor, read the directions for use enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor.

SPECIFICATIONS

Performance
Electrical
Environmental Conditions
Physical Characteristics

PERFORMANCE

Measurement Range

SpO₂

0–100%

Pulse Rate

20–250 beats per minute (bpm)

Accuracy

SpO₂

Adults	70–100%	±2 digits
	0–69%	unspecified
Neonates	70–100%	±3 digits
	0–69%	unspecified

Note: Accuracies are expressed as plus or minus “X” digits (oxygen saturation percentage points) between saturations of 70–100%. This variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population. All accuracy specifications are based on testing the subject monitor on healthy adult volunteers in induced hypoxia studies across the specified range. Adult accuracy is determined with *Oxisensor II* D-25 sensors. Neonatal accuracy is determined with *Oxisensor II* N-25 sensors. In addition, the neonatal accuracy specification is adjusted to take into account the theoretical effect of fetal hemoglobin in neonatal blood on oximetry measurements.

Specifications

Pulse Rate

20–250 bpm ± 3 bpm

Note: Pulse Rate accuracy is expressed as ± 3 bpm across the display range. This variation equals \pm one standard deviation (1SD), which encompasses 68% of the population.

Pulse Rate Display Update Frequency

The Pulse Rate Display updates in less than 2.5 seconds with a one-second change in SpO₂-derived pulse rate from 30 pulses per minute (ppm) to 200 ppm.

Radiated Immunity

The NPB-195 is immune to radiated radio-frequency electromagnetic fields of up to 3 volts per meter from 80 MHz to 1 GHz.

Conducted Immunity

The NPB-195 is immune to conducted radio-frequency electromagnetic energy of up to 3 volts from 150 kHz to 80 MHz.

ELECTRICAL

Instrument

Power Requirements

100 - 120 VAC, 200 -240 VAC, 50/60 Hz, 20 VA

Patient Isolation

Type BF

Battery

Type

Lead-Acid

Specifications

Battery Capacity

A minimum of 6 hours with a new, fully charged battery with no alarms and no backlight. A completely discharged battery can be fully recharged in approximately 14 hours while turned off or 18 hours while turned on.

Charge/discharge cycles: at least 400

ENVIRONMENTAL CONDITIONS

Transport and Storage (in shipping container)

Temperature

- 20 to 70°C (-4°F to +158°F)

Altitude/Barometric Pressure

- 457 m to 4,573 m (-1280 ft. to 15,000 ft.)
1060 hPa to 500 hPa (31.3 in. Hg to +14 in. Hg)

Relative Humidity

15-95% noncondensing

Transport and Storage (not in shipping container)

Temperature

- 20°C to +60°C (-4°F to +140°F)

Altitude/Barometric Pressure

- 457 m to 4,573 m (-1280 ft. to 15,000 ft.)
1060 hPa to 500 hPa (31.3 in. Hg to +14 in. Hg)

Relative Humidity

15-95% noncondensing over temperature range of -20°C to 60°C
(-4°F to +140°F)

Specifications

Operation

Temperature

+5°C to +40°C (+41°F to +104°F)

Altitude/Barometric Pressure

• 390 m to 3,658 m (-1280 ft. to 12,000 ft.)

+1060 hPa to +700 hPa (+31.3 in. Hg to +20.6 in. Hg)

Relative Humidity

15-95% noncondensing

PHYSICAL CHARACTERISTICS

Weight

5.7 lbs.

2.6 kg

Dimensions

3.3 in. x 10.4 in. x 6.8 in.

8.4 cm x 26.4 cm x 17.3 cm

Emissions Compliance

EN55011 Emissions Classification

CISPR 11, Group 1, Class B

Equipment Classification (IEC 601-1 / CSA 601.1 / UL 2601-1)

Type of Protection

Class 1 (on AC power)

Internally powered (on battery power)

Specifications

Degree of Protection

Type BF - Applied part

Enclosure Degree of Ingress Protection from Solids/Liquid

IPX1

Mode of Operation

Continuous

APPENDIX A: QUICK GUIDE TO OPERATION

Introduction

Settings Adjustments

INTRODUCTION

This *Quick Guide to Operation* is intended for use by experienced NPB-195 users. First-time users of the monitor should read the entire manual before use.






Ensure the rear panel voltage selector switch is set to the proper voltage. To turn the monitor on or off press













SETTINGS ADJUSTMENTS

Table 4 contains the procedures necessary to adjust or view the basic NPB-195 settings. In general, press EXIT to return to the main menu.



Table 4: Settings Adjustments

To Adjust	Action	Button
Pulse Beep Volume	Press and hold	 or 
Contrast	Press and hold	
	Press	 or 
Pleth or Magnified (blip) View	Press	SETUP
	Press	VIEW
	Select	PLETH or BLIP
	Press	EXIT

Appendix A: Quick Guide to Operation

Alarm Limits	Press Press (to select parameter) Press Press	LIMITS SELECT  or  EXIT
Alarm Volume	Press and hold (for <i>more</i> than 3 seconds) then, Press	  or 
Alarm Silence Duration	Press and hold (for <i>less</i> than 3 seconds) then, Press	  or 
Time and Date Settings	Press Press Press Press (to select setting) Press Press (to return to main menu)	SETUP CLOCK SET SELECT  or  EXIT, EXIT, EXIT
Trends	Press Press Select desired view	TREND VIEW

Appendix A: Quick Guide to Operation

Language	Press	SETUP
	Press	NEXT
	Press	LANG
	Press	 or 
	Press	EXIT

APPENDIX B: PRINCIPLES OF OPERATION

Oximetry Overview

OXIMETRY OVERVIEW

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO₂ measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Appendix B: Principles of Operation

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO₂. During manufacturing, the mean wavelength of the red LED is encoded in a resistor in the sensor.

During monitoring, the instrument's software reads this resistor and selects coefficients that are appropriate for the wavelength of that sensor's red LED; these coefficients are then used to determine SpO₂. This resistor is read when the monitor is turned on, periodically thereafter, and each time a new sensor is connected.

Additionally, to compensate for differences in tissue thickness, the intensity of the sensor's LEDs are adjusted automatically.

Functional versus Fractional Saturation

This monitor measures functional saturation — oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation — oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\% \text{ carboxyhemoglobin} + \% \text{ methemoglobin})} \times 100$$

Appendix B: Principles of Operation

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation (Figure 11): pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin.

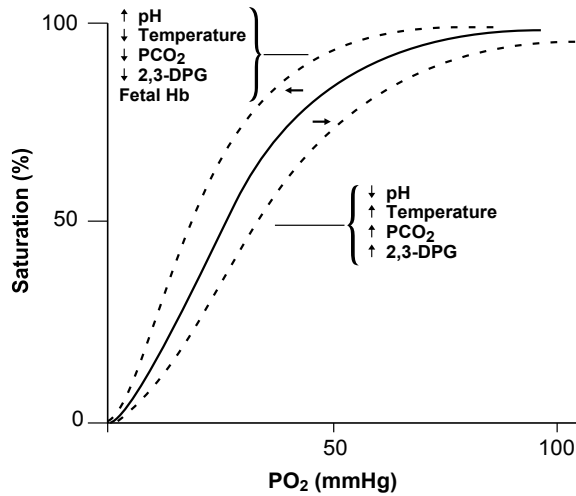


Figure 11: Oxyhemoglobin Dissociation Curve

APPENDIX C: DATA PORT PROTOCOL

Overview
Connecting to the Data Port
Baud Rate
Real-Time Display Format
Trend Data Printout

OVERVIEW

Patient data can be accessed through the data port on the back of the NPB-195 by connecting it to an attached PC or serial printer.

When connecting the NPB-195 to a printer or PC, verify proper operation before clinical use. Both the NPB-195 and the printer or PC must be connected to a grounded AC outlet.

Any printer or PC connected to the monitor's data port must be certified according to IEC Standard 950. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1 and the electromagnetic compatibility system standard IEC Standard 601-1-2.

CONNECTING TO THE DATA PORT

The NPB-195 data port may be connected to the printer or PC by using a cable terminated with an AMP connector (AMP part number 747538-1), ferrule (AMP part number 1-747579-2), and compatible pins (AMP part number 66570-2). The cable should be no more than 25 feet (7.6 meters) in length.

The cable used must have a braided shield providing 100% coverage, such as a Belden cable (Belden part number 9609) or equivalent. The shield must have a 360-degree connection to the metal shell on the NPB-195's DB-15 connector and to the connector on the PC or serial printer. Do not create sharp bends in the cable, as this may tear or break the shielding.

The pinouts (as illustrated in Figure 12) for the data port are listed in Table 5. Data is provided in RS-232 format.

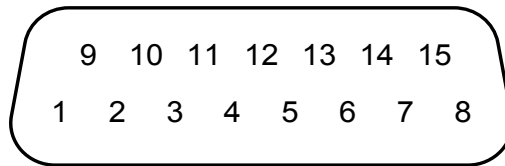
Appendix C: Data Port Protocol

Table 5: Data Port Pinouts

Pin	Line
2	RxD (Receive Data line)
3	TxD (Transmit Data line)
5, 10	Signal Ground (isolated from Earth Ground)
11	Nurse Call
1, 4, 6-9, 12-15	No Connection

GND is ground, TxD represents the Transmit Data line, and RxD is the Receive Data line.

The pin layouts (as viewed from the rear panel of the NPB-195) are illustrated in Figure 12. The conductive shell is connected to earth ground when connected to a PC or printer.

**Figure 12: Data Port Pin Layout****BAUD RATE**

The baud rate can be changed by pressing the SETUP softkey, the NEXT softkey, and then the COMM softkey. Use the Adjust Up/Down Buttons to select a baud rate of 2400, 9600, or 19200, depending on the capabilities of the attached equipment.

REAL-TIME DISPLAY FORMAT

While on AC power, real-time data is continuously sent to the data port on the back of the NPB-195. Patient data can be obtained through the data port by connecting it to an attached PC or serial printer. When a real-time printout or display is being transmitted to a printer or PC, a new line of data is displayed every 2 seconds. Column headings will be displayed or printed after every 25 lines, or if one of the values in the column heading changes.

Data cannot be obtained if the NPB-195 is operating on battery power.

Appendix C: Data Port Protocol

Note: If the data output stops transmitting, turn the power off and back on again or, if connected to a PC, send an XON (Ctrl-q) to reset the monitor.

An example of a real-time printout is shown in Figure 13.

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:05	100	120	50	
12-NOV-98 14:00:07	100	124	50	
12-NOV-98 14:00:09	100	190*	52	PH
12-NOV-98 14:00:11	100	190*	50	PH
12-NOV-98 14:00:13	100	190*	51	PH
12-NOV-98 14:00:15	100	190*	50	PH
12-NOV-98 14:00:17	100	190*	50	PH
12-NOV-98 14:00:19	100	190*	51	PH
12-NOV-98 14:00:21	100	190*	53	PH LB
12-NOV-98 14:00:23	100	190*	50	PH LB
12-NOV-98 14:00:25	100	190*	50	PH LB
12-NOV-98 14:00:27	---	---	---	SD LB
12-NOV-98 14:00:29	---	---	---	SD LB
12-NOV-98 14:00:31	---	---	---	SD
12-NOV-98 14:00:33	---	---	---	SD
12-NOV-98 14:00:35	---	---	---	SD
12-NOV-98 14:00:37	---	---	---	SD
12-NOV-98 14:00:39	---	---	---	SD
12-NOV-98 14:00:41	---	---	---	SD
12-NOV-98 14:00:43	---	---	---	SD
12-NOV-98 14:00:45	---	---	---	SD
12-NOV-98 14:00:47	---	---	---	SD
12-NOV-98 14:00:49	---	---	---	SD
NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:51	---	---	---	SD
NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 80-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:53	79*	59*	50	SL PL LB
12-NOV-98 14:00:55	79*	59*	52	PS SL PL LB

Figure 13: Real-Time Printout

Column Headings

Every 25th line of the data is a column heading.

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status

A column heading is also displayed whenever a value of the column heading is changed. There are three column heading lines shown in Figure 13. Using the top row as the starting point there

Appendix C: Data Port Protocol

are 25 lines before the second column heading is printed. The third column heading was displayed because the SpO2 limits changed from 30-100% to 80-100%.

Data Source

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status

Data in the highlighted box above represents the model number of the monitor, in this case the NPB-195.

Software Revision Level

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status

The next data field tells the user the software level, (Version 1.0.0.1) and a software verification number (CRC: XXXX). Neither of these numbers should change during normal operation. The numbers may change if the monitor is serviced and receives a software upgrade.

Alarm Limits

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status

The last data field in the top line indicates the high and the low alarm limits for %SpO2 and for the pulse rate (PR). In the example above the low alarm limit for SpO2 is 30% and the high alarm limit is 100%. Pulse Rate alarm limits are 50 and 150 bpm.

Column Headings

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status

Actual column headings are in the second row of the column heading line. Patient data that is presented in the chart, from left to right, is the time that the patient data on the row was obtained, the current %SpO2 value being measured, the current Pulse Rate in beats per minute (BPM), the current Pulse Amplitude (PA), and the operating status of the NPB-195.

Patient Data and Operating Status**Time**

TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:05	100	120	50	

The Time column represents the NPB-195 real-time clock.

Appendix C: Data Port Protocol**Patient Data**

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:05	100	190*	50	

Patient data is highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this example the %SpO₂ is 100, and the pulse rate is 190 beats per minute. The "*" next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available three dashes (- - -) will be displayed.

PA is an indication of pulse amplitude. The number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information as an indication of a change in pulse volume, relative pulse strength, or circulation.

Operating Status

NPB-195	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:11	100	190*	50	PH

The Status column indicates alarm conditions and operating status of the NPB-195. In this example, the PH means that the pulse rate upper alarm limit (Pulse High) has been exceeded. A complete listing of the status codes is listed in Table 6. As many as 4 codes can be displayed at one time in the Status column.

Table 6: Status Codes

Code	Meaning
AO	Alarm Off
AS	Alarm Silence
LB	Low Battery
LP	Loss-of-Pulse
PH	Pulse Rate High Limit Alarm
PL	Pulse Rate Low Limit Alarm
PS	Pulse Search
SH	Sat High Limit Alarm
SL	Sat Low Limit Alarm
SD	Sensor Disconnect

Appendix C: Data Port Protocol

Note: A sensor disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the display or printout.

TREND DATA PRINTOUT

The format of data displayed when a trend printout is requested is similar to that of the real time data. The only differences are that “TREND” is displayed in the top row instead of the “CRC: XXXX” software verification number and there is no “Status” column.

Readings are displayed in 5-second intervals. The values on each row are an average for the 5-second period.

At the end of the printout an “Output Complete” line indicates that the transmission was successful. If the “Output Complete” line is not present, a corruption of the data may have been detected and the data should be ignored.

NPB-195	VERSION 1.0.0.1	TREND	SpO2 Limit: 30-100%	PR Limit: 50-150BPM
TIME	%SPO2	BPM	PA	
22-NOV-98 14:00:05	100	120	150	
22-NOV-98 14:00:10	100	121	154	
22-NOV-98 14:00:15	100	120	150	
Output Complete				

Figure 14: Trend Data Printout

Once a trend printout has begun, the NPB-195 must be turned off and back on again before a new trend printout can begin. A trend printout cannot be aborted without turning off the NPB-195 or the printer.

Trend Data Operation

Whenever the NPB-195 is turned on, it stores a “data point” in memory every 5 seconds. When a data point is stored, the NPB-195 determines whether any data stored is older than 24 hours. If so, the oldest data point is erased.

The following statements further describe trend data operation:

- Data older than 24 hours is erased at the rate of one point every 5 seconds whenever the instrument is turned on (regardless of whether it is actually monitoring patient data).

Appendix C: Data Port Protocol

- If the NPB-195 is turned on for more than 24 hours, it will contain no data older than 24 hours.
- If the monitor contains data older than 24 hours, that data can be printed from the serial port, but pints are being erased even as the print is occurring.
- Data that is older than 24 hours old can only be obtained from the serial port. It cannot be displayed on the front panel.

EXHIBIT 5



SERVICE MANUAL

Nellcor Symphony™ N-3000 Pulse Oximeter

To contact Nellcor Puritan Bennett's representative: In the United States, call 1-800-NELLCOR or 510 463-4000; outside the United States, call your local Nellcor Puritan Bennett representative.

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.



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Fax 510 463-4420

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To obtain information about a warranty, if any, for this product, contact Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.

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Covered by one or more of the following U.S. Patents and foreign equivalents: 4,621,643; 4,653,498; 4,700,708; 4,770,179; 4,869,254; 5,078,136; and 5,351,685.

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SECTION 1: INTRODUCTION

- 1.1 Manual Overview
 - 1.2 Warnings, Cautions, and Notes
 - 1.3 N-3000 Pulse Oximeter Description
 - 1.4 Related Documents
-

1.1 MANUAL OVERVIEW

This manual contains information for servicing the *Nellcor Symphony* model N-3000 pulse oximeter. Only qualified service personnel should service this product. Before servicing the N-3000, read the operator's manual carefully for a thorough understanding of operation.

1.2 WARNINGS, CAUTIONS, AND NOTES

This manual uses three terms that are important for proper operation of the monitor: Warning, Caution, and Note.

1.2.1 Warning

A warning precedes an action that may result in injury or death to the patient or user. Warnings are boxed and highlighted in boldface type.

1.2.2 Caution

A caution precedes an action that may result in damage to, or malfunction of, the monitor. Cautions are highlighted in boldface type.

1.2.3 Note

A note gives information that requires special attention.

1.3 N-3000 PULSE OXIMETER DESCRIPTION

The *Nellcor Symphony* N-3000 pulse oximeter is intended for continuous noninvasive monitoring of functional oxygen saturation and pulse rate for adult, pediatric, and neonatal patients in a hospital environment. It may be used during hospital transport and in protected mobile environments such as ambulances and helicopters when powered by its internal battery and protected from excessive moisture, such as direct exposure to rain.

The N-3000 can operate as a standalone monitor or it can be connected to (stacked with) the N-3100 blood pressure monitor.

The physical and operational characteristics of the monitor are described in the operator's manual and Section 9, *Specifications*, of this manual.

Figure 1-1 depicts the North American front panel of the N-3000 and the names of its displays and controls.

Section 1: Introduction

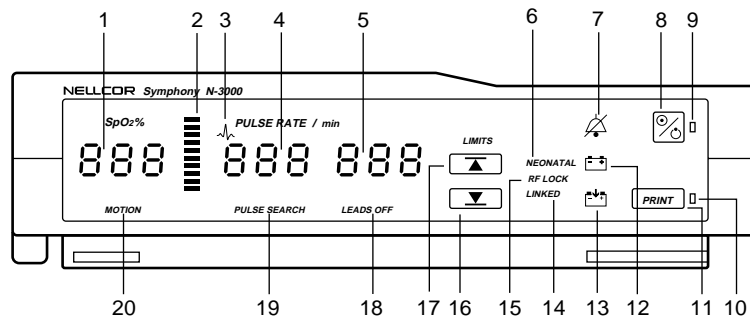


Figure 1-1: N-3000 Front Panel (North American)

- | | |
|--------------------------------|--|
| 1. SpO2% display | 11. PRINT button |
| 2. PULSE AMPLITUDE indicator | 12. BATTERY IN USE/BATTERY LOW indicator |
| 3. ECG HEART RATE indicator * | 13. BATTERY CHARGING indicator |
| 4. PULSE RATE display | 14. LINKED indicator* |
| 5. AUXILIARY display | 15. RF LOCKED indicator* |
| 6. NEONATAL MODE indicator | 16. LOWER ALARM LIMIT button |
| 7. AUDIBLE ALARM OFF indicator | 17. UPPER ALARM LIMIT button |
| 8. ON/STANDBY button | 18. LEADS OFF indicator* |
| 9. POWER ON indicator | 19. PULSE SEARCH indicator |
| 10. STACKED indicator | 20. PATIENT MOTION indicator |

* Not used on this model

1.4 RELATED DOCUMENTS

To perform test and troubleshooting procedures and to understand the principles of operation and circuit analysis sections of this manual, you must know how to operate the monitor. Refer to the N-3000 operator's manual. To understand the various *Nellcor Puritan Bennett* sensors that work with the monitor, refer to the individual sensor directions for use.

SECTION 2: ROUTINE MAINTENANCE

- 2.1 Cleaning
 - 2.2 Periodic Safety and Functional Checks
 - 2.3 Batteries
-

2.1 CLEANING

Caution: Do not immerse the N-3000 or its accessories in liquid or use caustic or abrasive cleaners. Do not spray or pour any liquid on the monitor or its accessories.

To clean the N-3000, dampen a cloth with a commercial, nonabrasive cleaner and wipe the instrument exterior surfaces lightly. Do not allow any liquids to come in contact with the power connector, fuse holder, or switches. Do not allow any liquids to penetrate connectors or openings in the instrument cover. Wipe sensor extension cables with a damp cloth. For sensors, follow individual directions for use.

2.2 PERIODIC SAFETY AND FUNCTIONAL CHECKS

The following safety checks should be performed by a qualified service technician after any repair or opening of the case, upon return of the instrument from any use outside your institution's control, or every 2 years.

1. Inspect the exterior of the N-3000 and verify that there is no evidence of damage. Refer to Section 5, *Troubleshooting* for repair. If the N-3000 cannot be repaired, contact Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative.
2. Inspect safety labels for legibility. If labels are not legible, contact Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative.
3. Verify that the monitor performs properly as described in paragraph 3.3.
4. Perform the electrical safety tests detailed in paragraph 3.4. If the unit fails these electrical safety tests, do not attempt to repair, contact Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative.
5. Inspect fuse(s) for proper rating (F1: 1.0 Amp, 250 Volt, Slo-Blow and F2: 2.5 Amp, 250 Volt, Slo-Blow). If necessary, replace as described in paragraph 6.4.

2.3 BATTERIES

Nellcor Puritan Bennett recommends replacing instrument batteries at least every 2 years. To replace the batteries, refer to Section 6, *Disassembly Guide*.

If the N-3000 has been stored for more than 30 days, charge the battery as described in paragraph 3.3.2. A fully discharged battery requires a 14 hour charge for a full charge. A 6-hour charge is required for 1 hour of operating time.

SECTION 3: PERFORMANCE VERIFICATION

- 3.1 Introduction
 - 3.2 Equipment Needed
 - 3.3 Performance Tests
 - 3.4 Safety Tests
 - 3.5 SpO₂ Tests
 - 3.6 Piezo Speaker Test
-

3.1 INTRODUCTION

This section discusses the tests used to verify performance following troubleshooting and repairs. All tests are accomplished through the control panel.

3.2 EQUIPMENT NEEDED

Equipment	Description
AC Power Adapter	<i>Nellcor Puritan Bennett</i> model SPS-N or SPS-N1
Safety Analyzer	Must meet current AAMI specifications
Sensor Cable	SCP-10
Digital Multimeter (DMM)	Fluke Model 87 or equivalent
<i>Durasensor</i> [®] Oxygen Transducer	DS-100A
Serial Interface Cable	EIA-232 cable (optional)
Connector Adapter	6-pin, miniature
<i>Oxisensor</i> [®] II Oxygen Transducer	D-25
Pulse Oximeter Tester	SRC-2

3.3 PERFORMANCE TESTS

Note: The battery operation and battery charge tests should be performed before monitor repairs whenever the battery is suspected of being a source of the problems. All other tests should be performed following monitor repairs. Before performing the battery operation test, ensure that the battery is fully charged (Paragraph 3.3.2).

3.3.1 Battery Operation Test

The monitor is specified to operate on battery power a minimum of 4 hours. (This time may decrease if the N-3000 is operating in the stacked configuration.)

1. Connect the *Nellcor Puritan Bennett* SRC-2 pulse oximeter tester to the monitor.
2. Ensure that the monitor is not connected to AC power.

Section 3: Performance Verification

3. With the N-3000 turned off, press the ON/STANDBY button and verify that the BATTERY IN USE/BATTERY LOW indicator lights after the power-on self-test is completed.



4. The monitor must operate for at least 4 hours.
5. The BATTERY IN USE/BATTERY LOW indicator will start to flash about 15 minutes before the battery fully discharges.
6. Allow the monitor to operate until it automatically powers down due to the low battery.
7. If the monitor passes this test, immediately recharge the battery (Paragraph 3.3.2, steps 1 - 3).

3.3.2 Battery Charge

Perform this procedure to fully charge the battery or after the Battery Operation Test (Paragraph 3.3.1). This procedure should be performed, if possible, before repair work is attempted.

1. Connect the monitor to an AC power source using the external power supply.
2. Verify that the monitor is off and that the BATTERY CHARGING indicator is lit.



3. Charge the battery for at least 14 hours.

Note: The BATTERY CHARGING indicator is timed to go out when the N-3000 has been turned off and connected to AC power for 14 hours. Likewise, if the monitor is turned *on* and connected to AC power for 14 hours (with no power interruptions), the indicator goes out.

An illuminated BATTERY CHARGING indicator is not necessarily an indication that the battery contains less than a full charge. It is merely used as a timer to indicate that the battery has been continuously charging for less than 14 hours.

4. If unsure whether the battery is functioning properly, perform the procedure in Paragraph 3.3.1 "Battery Operation Test".
5. Repeat this procedure (3.3.2 "Battery Charge") through step 3 before returning the monitor to service.

3.3.3 Power-up Tests

The power-up tests (3.3.3.1 through 3.3.3.3) verify the following monitor functions:

- Power-On Self-Test
- Adult Power-On Defaults and Alarm Limit Ranges
- Neonate Power-On Defaults and Alarm Limit Ranges

3.3.3.1 Power-On Self-Test

1. Connect the monitor to an AC power source using the external power supply and verify that the BATTERY CHARGING indicator is lit.
2. Do not connect any sensor cables to the monitor.
3. Observe the monitor front panel. With the monitor off, press the ON/STANDBY button. To successfully complete the self-test, the monitor must perform the following sequence.
 - a. The monitor emits three consecutively higher pitched beeps.
 - b. All indicators light for a few seconds as illustrated in Figure 3-1. Verify that the SpO₂ % (left-most display), PULSE RATE (middle), and AUXILIARY (right) displays all indicate “8.8.8.”.

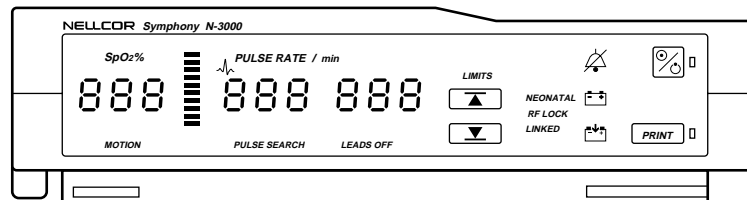


Figure 3-1: Self-Test Display

- c. All displays turn off momentarily.
- d. Digital displays individually light in a scanning, or firefly, test pattern while the test is taking place.
- e. A single, 1-second beep is produced and all displays again illuminate momentarily, indicating that the automatic power-on self-test is complete. The beep may sound before all the displays have lit in the scanning sequence.
- f. The POWER ON indicator and the BATTERY CHARGING indicator are illuminated. The SpO₂%, PULSE RATE, and AUXILIARY displays are blank. (If an SpO₂ sensor cable and sensor were connected, “0” would be displayed in both the SpO₂ % and PULSE RATE displays.) This is referred to as the normal mode steady state.
- g. Press and hold the NEW PATIENT/NEONATAL button (located on the rear panel) for 3 seconds until you hear three beeps, indicating that stored patient data is cleared.

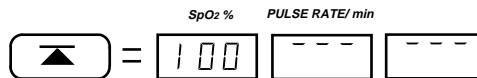
Section 3: Performance Verification

3.3.3.2 Adult Power-On Defaults and Alarm Limit Ranges

Note: This paragraph and paragraph 3.3.3.3 are written using Nellcor Puritan Bennett factory-set defaults. If your institution has preconfigured custom defaults, those values will be displayed. Factory defaults can be reset using the service mode procedure described in paragraph 4.3.11, Menu Item 20, Reset to Factory Defaults, or the configuration mode procedure described in paragraph 4.2.8.6.

When observing or changing default limits, a 3-second timeout is in effect, that is, if no action is taken within 3 seconds, the monitor automatically returns to the normal mode steady state.

1. Ensure that the monitor is on. Press and release the UPPER ALARM LIMIT button. Verify that the monitor emits a single beep and the SpO₂% display indicates an alarm limit of “100” for 3 seconds. Verify that the other displays indicate a single bar at the top of each window while the “100” is displayed.



At the end of the 3 seconds, the displays indicate dashes (normal mode steady state).

2. Press and release the UPPER ALARM LIMIT button. Begin rotating the control knob counterclockwise (CCW) within 3 seconds. Verify that the SpO₂% display reduces to a minimum of “85.”.

Note: A decimal point in the display indicates that the alarm limits have changed.

3. Press and release the LOWER ALARM LIMIT button. Verify that the monitor emits a single beep and the SpO₂% display indicates an alarm limit of “85” for 3 seconds. Verify that the other displays indicate a single bar at the bottom of each window while the “85” is displayed.
4. From the normal mode steady state, press and release the LOWER ALARM LIMIT button. Begin rotating the control knob CCW within 3 seconds. Verify that the SpO₂% display reduces to a minimum of “20”. Rotate the control knob clockwise (CW) and verify that the SpO₂% display cannot be raised past the upper alarm limit setting of “85”.
5. Press the UPPER ALARM LIMIT button two times rapidly (twice within 3 seconds). Verify that the monitor emits two beeps and the PULSE RATE display indicates an alarm limit of “170” for 3 seconds.
6. From the normal mode steady state, press the UPPER ALARM LIMIT button two times rapidly. Begin rotating the control knob CCW within 3 seconds. Verify that the PULSE RATE display reduces to a minimum of “40”.
7. Press the LOWER ALARM LIMIT button two times rapidly. Verify that the PULSE RATE display indicates an alarm limit of “40” for 3 seconds.
8. From the normal mode steady state, press the LOWER ALARM LIMIT button two times rapidly. Rotate the control knob CCW. Verify that the PULSE RATE display reduces to a minimum of “30”.

9. Press the AUDIBLE ALARM OFF button (located on top of the N-3000) and verify that the monitor emits a low-pitched beep when the button is pressed.
10. Press the ON/STANDBY button to turn the monitor off. Verify that the monitor emits three decreasing pitch beeps.
11. Observe the monitor front panel. Press the ON/STANDBY button. The monitor performs the sequence described in paragraph 3.3.3.1 (Power-On Self-Test), 3a through 3g.
12. Press and release the UPPER ALARM LIMIT button. Verify that the SpO₂% display indicates an alarm limit of “100”.
13. Press and release the LOWER ALARM LIMIT button. Verify that the SpO₂% display indicates an alarm limit of “85”.
14. Press the UPPER ALARM LIMIT button two times rapidly. Verify that the PULSE RATE display indicates an alarm limit of “170”.
15. Press the LOWER ALARM LIMIT button two times rapidly. Verify that the PULSE RATE display indicates an alarm limit of “40”.
16. Press the ON/STANDBY button to turn the monitor off.

3.3.3.3 Neonate Power-On Defaults and Alarm Limit Ranges

Note: When observing or changing default limits, a 3-second timeout is in effect, that is, if no action is taken within 3 seconds, the monitor automatically returns to the normal mode steady state.

1. Turn the monitor on.
2. Press the NEW PATIENT/NEONATAL button on the rear panel two times rapidly (twice within 2 seconds).
3. Verify that the NEONATAL MODE indicator on the front panel is lit.
4. From the normal mode steady state, press and release the UPPER ALARM LIMIT button. Verify that the SpO₂% display indicates an alarm limit of “95” for 3 seconds. Verify that the other displays indicate a single bar at the top of each window while the “95” is displayed.
5. From the normal mode steady state, press and release the UPPER ALARM LIMIT button. Begin rotating the control knob CCW within 3 seconds. Verify that the SpO₂% display reduces to a minimum of “80”.
6. From the normal mode steady state, press and release the LOWER ALARM LIMIT button. Verify that the SpO₂% display indicates an alarm limit of “80”. Verify that the other displays indicate a single bar at the bottom of each window while the “80” is displayed.
7. From the normal mode steady state, press and release the LOWER ALARM LIMIT button. Rotate the control knob CCW. Verify that the SpO₂% display reduces to a minimum of “20”. Rotate the knob CW to verify that the lower alarm limit cannot be raised past the upper alarm limit of 80.

Section 3: Performance Verification

8. Press the UPPER ALARM LIMIT button two times rapidly (twice within 3 seconds). Verify that the PULSE RATE display indicates an alarm limit of "190".
9. Press the LOWER ALARM LIMIT button twice rapidly. Verify that the PULSE RATE display indicates an alarm limit of "90".
10. Press the AUDIBLE ALARM OFF button and verify that the monitor emits a beep when the button is pressed.
11. Press the ON/STANDBY button to turn the monitor off.
12. Press the ON/STANDBY button to turn the monitor on. The monitor performs the sequence described in 3.3.3.1.

Note: The "NEO" indicator will not be lit.
13. Press and release the UPPER ALARM LIMIT button. Verify that the SpO₂% display indicates an alarm limit of "100".
14. Press and release the LOWER ALARM LIMIT button. Verify that the SpO₂% display indicates an alarm limit of "85".
15. Press the ON/STANDBY button to turn the monitor off.

This completes the power-up tests.

3.3.4 Operation with a Pulse Oximeter Tester

Operation with an SRC-2 pulse oximeter tester includes the following tests.

- 3.3.4.1 Alarms
- 3.3.4.2 Alarm Silence
- 3.3.4.3 Alarm Volume Control
- 3.3.4.4 Volume Control
- 3.3.4.5 Dynamic Operating Range

Note: This section is written using Nellcor Puritan Bennett factory-set defaults. If your institution has preconfigured custom defaults, those values will be displayed. Factory defaults can be reset using the service mode procedure described in Paragraph 4.3.11, Menu Item 20, Reset to Factory Defaults, or the configuration mode procedure described in paragraph 4.2.8.6.

3.3.4.1 Alarms

1. Connect the SRC-2 pulse oximeter tester to the sensor input cable and connect the cable to the monitor. Set the SRC-2 as follows:

<u>SWITCH</u>	<u>POSITION</u>
RATE	38
LIGHT	LOW
MODULATION	HIGH
MODE	LOC/RCAL 63

2. Press and release the ON/STANDBY button to turn the monitor on. After the normal power-up sequence, verify that the SpO₂% and PULSE RATE displays initially indicate zeroes.

Note: The pulse bar may occasionally indicate a step change as the monitor is in the pulse search mode.

3. Verify the following monitor reaction:
 - a. The pulse bar begins to track the artificial pulse signal from the SRC-2.
 - b. After at least five pulses, the monitor displays a saturation and pulse rate within the following tolerances:

Oxygen Saturation Range	79 to 83%
Pulse Rate Range	37 to 39 bpm
 - c. The pulse “beep” will be heard.
 - d. The audio alarm will sound and both the SpO₂% and PULSE RATE display will flash, indicating both parameters have violated the default alarm limits. To silence the alarm, continue with the following paragraph.

3.3.4.2 Alarm Silence

After completing paragraph 3.3.4.1:

1. Press and hold the AUDIBLE ALARM OFF button on the top of the monitor. The alarm is silenced. The PULSE RATE display indicates “60” and the AUXILIARY display indicates “SEC” while the AUDIBLE ALARM OFF button is pressed.
2. Release the AUDIBLE ALARM OFF button. Verify the following:
 - a. The alarm remains silenced.
 - b. The AUDIBLE ALARM OFF indicator lights.
 - c. The SpO₂% and PULSE RATE displays resume flashing.
 - d. The pulse tone is still audible.
 - e. The audio alarm returns approximately 60 seconds after the AUDIBLE ALARM OFF button is released.
3. Press and hold the AUDIBLE ALARM OFF button. Rotate the control knob CCW until the PULSE RATE display indicates “30 SEC”. Rotate the control knob clockwise (CW) and verify that the displays indicate 60 SEC, 90 SEC, 120 SEC, and OFF. Release the button when the display indicates “OFF”. Verify that the AUDIBLE ALARM OFF indicator flashes.
4. Wait approximately 3 minutes. Verify that the alarm does not return. After 3 minutes, the alarm silence reminder beeps three times, and will continue to do so at 3-minute intervals.

Section 3: Performance Verification

3.3.4.3 Alarm Volume Control

After completing paragraph 3.3.4.2:

1. Press and hold the AUDIBLE ALARM OFF button on the top of the monitor. Verify the following:
 - a. "OFF" is displayed for approximately 3 seconds.
 - b. After 3 seconds, a steady tone is heard at the default alarm volume setting, the PULSE RATE display indicates "VOL", and the AUXILIARY display indicates the current default setting.
2. While continuing to hold the AUDIBLE ALARM OFF button, rotate the control knob CCW to decrease the alarm volume setting to a minimum value of 1. The alarm tone should still be audible. Rotate the control knob CW to increase the alarm volume setting to a maximum value of 10. Rotate the knob until a comfortable audio level is attained.
3. Release the AUDIBLE ALARM OFF button. The tone will stop.

3.3.4.4 Pulse Tone Volume Control

1. Rotate the control knob CW and verify that the beeping pulse tone sound level increases.
2. Rotate the control knob CCW and verify that the beeping pulse tone can be turned off completely. Rotate the knob CW until a comfortable audio level is attained.

3.3.4.5 Dynamic Operating Range

The following test sequence will verify proper monitor operation over a wide range of input signals.

Note: The N-3000 pulse qualification may occasionally reject some pulses from the SRC-2 pulse oximeter tester. This is indicated by the missing audible pulse tone and the illuminated PATIENT MOTION indicator.

1. Verify that the monitor is still displaying saturation and that pulse information is in compliance with the SRC-2 tolerance. Both displays are still flashing due to alarm limit violation.

Oxygen Saturation Range:	79 to 83%
Pulse Rate Range:	37 to 39 bpm

2. Ensure the MODULATION switch on the SRC-2 is set to HIGH and verify that after a few seconds the monitor indications are within the tolerances listed in step 1.
3. Move the MODULATION switch to LOW and verify that after a few seconds the monitor indications are within the tolerances listed in step 1.
4. Move the LIGHT switch to HIGH 2 and verify that after a few seconds the monitor indications are within the tolerances listed in step 1.
5. Move the MODULATION switch to HIGH and verify that after a few seconds the monitor indications are within the tolerances listed in step 1.

6. Move the RATE switch to 112 bpm. After approximately 30 seconds, verify that the PULSE RATE display has stopped flashing and that the display indications are within the tolerances shown below:

Oxygen Saturation Range:	79 to 83%
Pulse Rate Range:	110 to 114 bpm

Note: If the unit has been configured for the “latching alarm ON” setting, the HEART/PULSE RATE display continues to flash, despite the pulse rate being within upper and lower alarm limits. Press the AUDIBLE ALARM OFF button to stop the flashing. Refer to paragraph 4.3.13 to place the unit in the “latching alarm OFF” setting.

7. Move the MODULATION switch to LOW and verify that after a few seconds the monitor indications are within the tolerances listed in step 6.
8. With the LIGHT switch set to HIGH 2, verify that after a few seconds the monitor indications are within the tolerances listed in step 6.
9. Move the MODULATION switch to HIGH and verify that after a few seconds the monitor indications are within the tolerances listed in step 6.
10. Move the LIGHT switch to LOW and verify that after a few seconds the monitor indications are within the tolerances listed in step 6.
11. Move the MODULATION switch to LOW and verify that after a few seconds the monitor indications are within the tolerances listed in step 6.
12. Move the RATE switch to 201 bpm. After approximately 30 seconds, verify that the PULSE RATE display is flashing and the display indications are within the tolerances shown below:

Oxygen Saturation Range:	79 to 83%
Pulse Rate Range:	195 to 207 bpm

13. Move the MODULATION switch to HIGH and verify that after a few seconds the monitor indications are within the tolerances listed in step 12.
14. Move the LIGHT switch to HIGH 1 and verify that after a few seconds the monitor indications are within the tolerances listed in step 12.
15. Move the MODULATION switch to LOW and verify that after a few seconds the monitor indications are within the tolerances listed in step 12.
16. Move the LIGHT switch to HIGH 2 and verify that after a few seconds the monitor indications are within the tolerances listed in step 12.
17. With the MODULATION switch to LOW, verify that after a few seconds the monitor indications are within the tolerances listed in step 12.
18. Turn the N-3000 off. Disconnect the tester from the cable.

Section 3: Performance Verification

3.3.5 Normal Operation

The following tests are an overall performance check of the system:

- LED Excitation Test
- Operation with a Live Subject
- Serial Interface Test

3.3.5.1 LED Excitation Test

This procedure uses normal system components to test circuit operation. A *Nellcor Puritan Bennett Oxisensor II* oxygen transducer, model D-25, is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.

1. Connect the monitor to an AC power source through the SPS power supply.
2. Connect an SCP-10 sensor input cable to the monitor.
3. Connect a D-25 sensor to the sensor input cable.
4. Press the ON/STANDBY button to turn the monitor on.
5. Leave the sensor open with the LEDs and photodetector visible.
6. After the monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.
7. Slowly move the sensor LED in proximity to the photodetector element of the sensor. Verify, as the LED approaches the optical sensor, that the LED intensity decreases.
8. Open the sensor and notice that the LED intensity increases.
9. Repeat step 7 and the intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.
10. Turn the N-3000 off.

3.3.5.2 Operation with a Live Subject

Patient monitoring involves connecting the monitor to a live subject for a qualitative test.

1. Connect the N-3000 to an AC power source.
2. Connect an SCP-10 sensor input cable to the monitor.
3. Connect a *Nellcor Puritan Bennett Durasensor* oxygen transducer, model DS-100A, to the sensor input cable.
4. Clip the DS-100A to the subject as recommended in the sensor directions for use.
5. Press the ON/STANDBY button to turn the monitor on.
6. The monitor should stabilize on the subject's physiological signal in about 10 to 15 seconds. Verify that the saturation and pulse rates are reasonable for the subject.

3.3.5.3 Serial Interface Test

The communications submodule of the N-3000, using an asynchronous, EIA-232 communications format, allows communications between the N-3000 and a PC, via the 6-pin connector on the rear panel of the N-3000, as illustrated in Figure 3-2. An EIA-232 cable and detailed directions for use are available by contacting your local Nellcor Puritan Bennett representative.

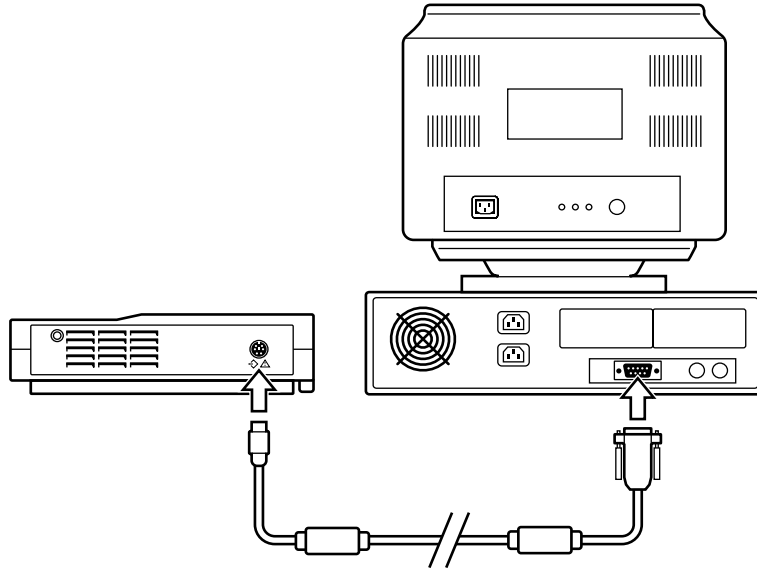


Figure 3-2: Serial Port Interface

The serial port can also be used to provide remote monitoring of alarms when configured as explained in paragraph 4.4, Alarm Active Function.

The two configurable options of serial data interface are RS-232 and EIA-422. The N-3000 is shipped with the RS-232 setting. To change the settings, refer to paragraph 6.5.1.

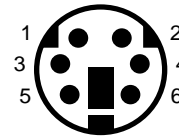
Perform the following procedure to test the serial port voltages.

1. Connect the monitor to an AC power source through the SPS power supply and turn the monitor on. (The serial port is functional only when the N-3000 is operated from an AC power source.)
2. Connect a 6-pin miniature connector adapter to the serial interface port.
3. Set up the DMM as follows:

Function:	VDC
Range:	10 V
4. Connect the DMM negative lead to connector pin 4 (GND).

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5. Connect the DMM positive lead to the following pins and verify the voltage values listed in Table 3-1.



**Serial Port Connector
External Pin Locations**

Table 3-1: Serial Port Voltages

Pin	Line	Voltage
1	DTR	7.5 ± 2.5
2	DSR	0.0 ± 0.4
3	TXD	-7.5 ± 2.5
4	GND	0.0 ± 0.4
5	RXD	0.0 ± 0.4
6	Alarm Active*	0.0 ± 0.4 or 3.3 ± 0.4

*Allows alarm activity to be monitored from a location away from the N-3000 (refer to paragraph 4.4).

Connections between the N-3000 serial port and an external PC are as indicated in Figure 3-3.

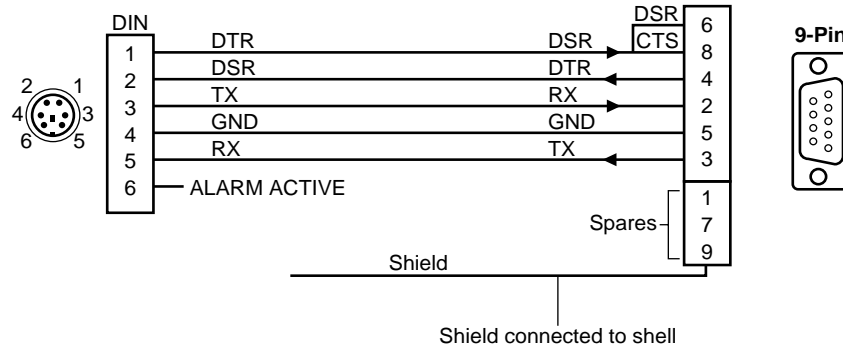


Figure 3-3: N-3000 to External PC Connections

3.4 SAFETY TESTS

N-3000 safety tests consist of:

- Ground Integrity
- Electrical Leakage

3.4.1 Ground Integrity

This test verifies the integrity of the power cord ground wire from the AC plug and connection with the SPS external power supply chassis ground.

1. Configure the electrical safety analyzer as follows:

Function:	Ground resistance test
Range:	mΩ

2. Connect the monitor's AC plug to the analyzer as recommended by the analyzer operating instructions.
3. Connect the analyzer "resistance" input lead to the grounding lug on the rear panel of the external power supply. Verify that the analyzer indicates 150 milliohms or less.

3.4.2 Electrical Leakage

The following tests verify the electrical leakage of the monitor.

- Chassis Source Current
- Patient Source Current
- Patient Sink Current

3.4.2.1 Chassis Source Current

This test is in compliance with IEC 601.1 and AAMI Standard ES1, Paragraph 3.3.1, Chassis Source Current, between the power ground and (part b), exposed conductive hardware.

1. Configure the electrical safety analyzer as follows:

Function:	Leakage
Range:	μA

2. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
3. Connect the electrical safety analyzer "leakage" input lead to the monitor's SPS external power supply grounding lug.

The analyzer leakage indication must not exceed 100 microamps at 100-120 VAC or 500 microamps at 220-240 VAC for the following AC power configurations while the monitor is turned on or while turned off.

<u>AC LINE</u> <u>POLARITY</u>	<u>POWER LINE</u> <u>GROUND CABLE</u>
Normal	Normal
Reverse	Normal
Reverse	Open
Normal	Open

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3.4.2.2 Patient Source Current

This test is in compliance with AAMI Standard ES1, Paragraph 3.3.2. Patient Source Current is measured between any individual patient connection and power (earth) ground.

1. Configure the electrical safety analyzer as follows:

Function: Leakage
Range: μA

2. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions for patient source current.
3. Connect the electrical safety analyzer leakage input lead to the monitor's sensor input connector.

The analyzer leakage indication must not exceed 10 microamps for all of the following AC power configurations with the monitor on.

<u>AC LINE</u> <u>POLARITY</u>	<u>POWER LINE</u> <u>GROUND CABLE</u>
Normal	Normal
Reverse	Normal
Reverse	Open
Normal	Open

3.4.2.3 Patient Sink Current

This test is in compliance with AAMI Standard ES1, Paragraph 4.4. Patient sink current is measured in a patient connection if a source of 240 volts, 50 Hz (or 120 volts, 60 Hz) with respect to power (earth) ground, is connected to that patient connection.

1. Configure the electrical safety analyzer as follows:

Function: Leakage
Range: μA

2. Connect the monitor AC plug to the electrical safety analyzer as recommended by the operating instructions for patient sink current.
3. Connect the electrical safety analyzer leakage input lead to the monitor's sensor input.

The analyzer leakage indication must not exceed 50 microamps for 240 volts (10 microamps for 120 volts) for the following AC power configurations with the monitor on.

<u>AC LINE</u> <u>POLARITY</u>	<u>POWER LINE</u> <u>GROUND CABLE</u>
Normal	Normal
Normal	Open

3.5 SPO₂ TESTS

The following tests can be used to verify, analyze, and troubleshoot the SpO₂ circuitry of the N-3000:

- RCAL Circuit Test
- LED Drive Tests

The tests require use of the SRC-2 tester and the service mode configuration, as detailed in paragraph 4.3.

3.5.1 RCAL Circuit Test

1. Connect an SRC-2 pulse oximeter tester to the sensor input cable and connect the cable to the monitor.
2. Set the SRC-2 as follows:

<u>SWITCH</u>	<u>POSITION</u>
RATE	112
LIGHT	LOW
MODULATION	OFF
MODE	LOC/RCAL 63

3. Enter the service mode steady state, as instructed in paragraph 4.3.
4. Select menu item 30 by rotating the knob until “30” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
5. The RCAL value “63” is displayed in the PULSE RATE display.
6. Set the SRC-2 RCAL/Mode switch to REM/RCAL 64. The RCAL value “64” is displayed in the PULSE RATE display.
7. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

3.5.2 LED Drive Tests

1. Connect an SRC-2 pulse oximeter tester to the sensor input cable and connect the cable to the monitor.
2. Set the SRC-2 as follows:

<u>SWITCH</u>	<u>POSITION</u>
RATE	112
LIGHT	LOW
MODULATION	OFF
MODE	REM/RCAL 63

3. If you are not already in the service mode, enter the service mode steady state, as instructed in paragraph 4.3.
4. Select menu item 33 by rotating the knob until “33” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
5. The SpO₂ IR LED drive value “170” is displayed in the PULSE RATE display. The IR indicator on the SRC-2 is illuminated.

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6. Rotate the knob to adjust the IR LED drive level indicated in the PULSE RATE display to 255.
7. While watching the IR indicator on the SRC-2, confirm the setting by pressing the UPPER ALARM LIMIT button. The LED intensity should increase.
8. Rotate the knob to adjust the IR LED drive level indicated in the PULSE RATE display to 0.
9. Press the UPPER ALARM LIMIT button. The IR LED should turn off.
10. Rotate the knob to adjust the IR LED drive level indicated in the PULSE RATE display to 170.
11. Press the UPPER ALARM LIMIT button. The IR LED intensity should increase.
12. Press the LOWER ALARM LIMIT button to return to the service mode steady state.
13. Select menu item 34 by rotating the knob until "34" appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
14. The SpO₂ red LED drive value "170" is displayed in the PULSE RATE display. The IR indicator on the SRC-2 is illuminated.
15. Rotate the knob to adjust the red LED drive level indicated in the PULSE RATE display to 255.
16. While watching the RED indicator on the SRC-2, confirm the setting by pressing the UPPER ALARM LIMIT button. The LED intensity should increase.
17. Rotate the knob to adjust the red LED drive level indicated in the PULSE RATE display to 0.
18. Press the UPPER ALARM LIMIT button. The RED indicator should turn off.
19. Rotate the knob to adjust the red LED drive level indicated in the PULSE RATE display to 170.
20. Press the UPPER ALARM LIMIT button. The RED indicator intensity should increase.
21. Press the LOWER ALARM LIMIT button to return to the service mode steady state.
22. Press the ON/STANDBY button to turn the N-3000 off.

3.6 PIEZO SPEAKER TEST

The following test verifies that the piezo power loss alarm speaker sounds an alarm when the N-3000 loses power.

WARNING: Before attempting to open or disassemble the N-3000, disconnect the power cord from the N-3000.

Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.

1. Ensure that the N-3000 is turned off.
2. Disconnect the monitor from the SPS power supply.
3. Set the N-3000 upside down facing you, as shown in Figure 3-4.

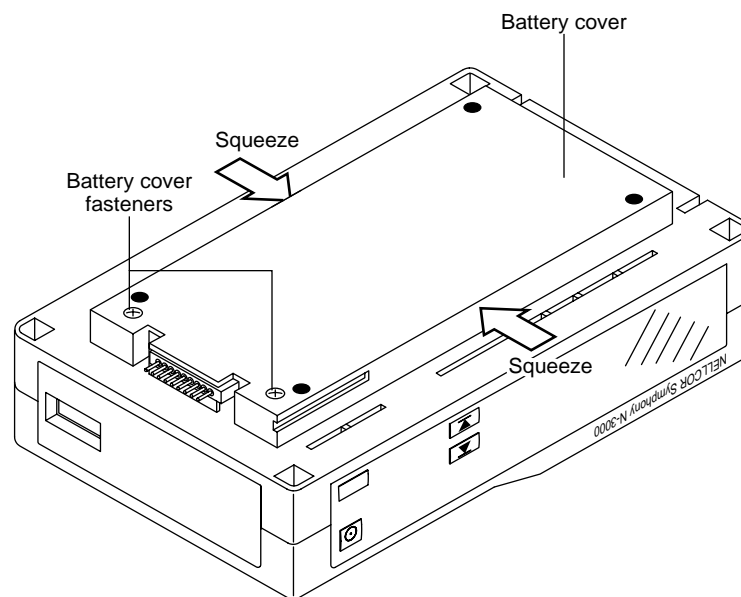


Figure 3-4: Battery Cover Removal

4. Using a small, Phillips-head screwdriver, loosen the two battery cover retaining fasteners securing the battery compartment cover.
5. Gently squeeze the battery cover sides in the middle as you swing the cover open (it is hinged on the right with three tabs that extend into slots on the chassis).
6. Lift the battery out of the compartment, as shown in Figure 3-5. It may be necessary to use the edge of a flat tip screwdriver to gently pry the battery loose.

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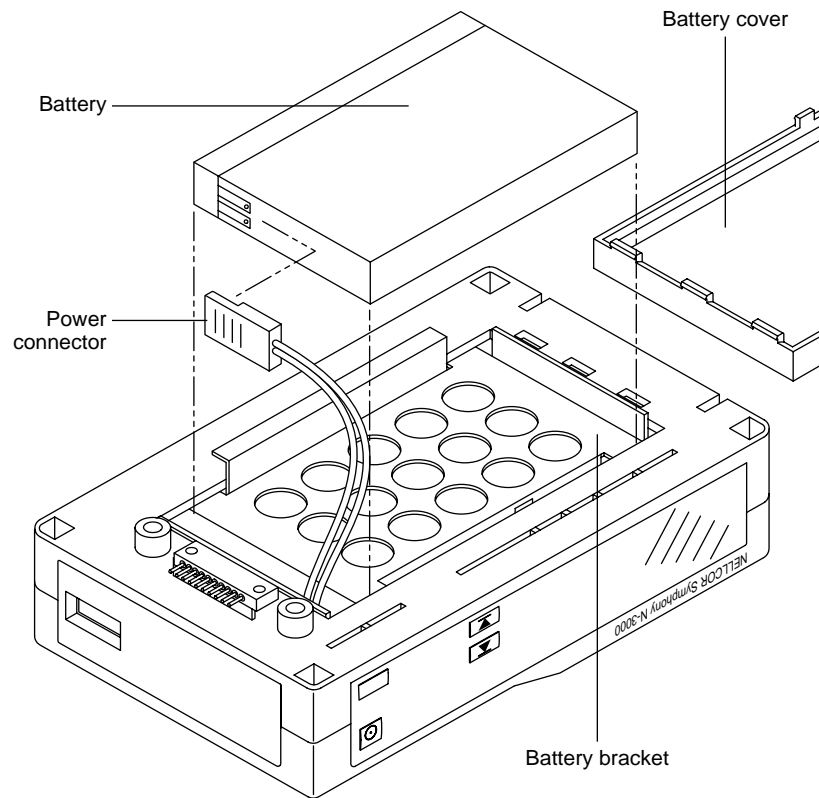


Figure 3-5: Speaker Test

7. Turn the monitor on by pressing the ON/STANDBY button.
8. When the power-on self-test is complete, disconnect the power connector from the battery. Verify that a shrill, beeping alarm is emitted from the speaker. If no alarm sounds, check the functionality of the lithium backup battery as indicated in paragraph 4.3.9, menu item 18.2 of the service mode. The battery should measure approximately 3 volts. If the battery is good, replace the UIF PCB as indicated in paragraph 6.8.
9. Reconnect the power connector to the battery. The alarm is silenced and the monitor powers back on.
10. Turn the monitor off by pressing the ON/STANDBY button.
11. Replace the battery in the battery bracket and reconnect the battery cover.

SECTION 4: CONFIGURATION MODE, SERVICE MODE, AND ALARM ACTIVE FUNCTION

- 4.1 Introduction
 - 4.2 Configuration Mode
 - 4.3 Service Mode
 - 4.4 Alarm Active Function
-

4.1 INTRODUCTION

This section discusses use of the configuration mode to reconfigure power-on default values, the service mode to identify and correct monitor difficulties, and the alarm active function.

4.2 CONFIGURATION MODE

The following paragraphs describe how to enter the N-3000 configuration mode and change factory power-on default settings.

The N-3000 cannot enter the configuration mode while it is stacked unless the N-3100 is in the configuration mode or is turned off. If both instruments are in the configuration mode, the N-3000 knob may be used to scroll to the desired menu item and adjust the settings of the N-3100.

Use the following procedure to enter configuration mode:

1. If the monitor is on, turn it off.
2. While simultaneously pressing both UPPER and LOWER ALARM LIMIT buttons, turn the monitor on. Continue to press both buttons until "CFG" begins flashing in the AUXILIARY display.
3. Release the UPPER and LOWER ALARM LIMIT buttons.
4. Press the PRINT button. "CFG" stops flashing and remains displayed in the AUXILIARY display. (If the PRINT button is not pressed within 15 seconds after "CFG" begins flashing, the monitor will turn off automatically.)

You are now in configuration mode steady state. The N-3000 automatically powers down if no action is taken for approximately 2 minutes.

After changing or viewing a default setting, you can return to the configuration mode steady state by allowing the display to timeout (3 seconds).

To exit the configuration mode, turn the monitor off by pressing the ON/STANDBY button. Default settings take place when the monitor is turned off. Default settings also take place if the N-3000 powers down due to the 2-minute timeout.

Section 4: Configuration Mode, Service Mode, and Alarm Active Function

Note: While changing default limits, there must be some user interaction with the monitor within a 3-second period or the monitor will return to configuration mode steady state operation.

Table 4-1 lists the default settings that can be configured and the respective entry procedures to access the settings. Methods used to change the default settings are detailed in paragraphs 4.2.1 through 4.2.8.

Table 4-1: Configuration Mode Menu

Power on Default Setting	Button Press Procedure from Configuration Mode Steady State	Paragraph Described
Adult/Neonatal Mode	NEW PATIENT/NEONATAL button twice	4.2.1
SpO ₂ Upper Alarm Limit	UPPER ALARM LIMIT button	4.2.2
SpO ₂ Lower Alarm Limit	LOWER ALARM LIMIT button	4.2.3
Pulse Rate Upper Alarm Limit	UPPER ALARM LIMIT button twice	4.2.4
Pulse Rate Lower Alarm Limit	LOWER ALARM LIMIT button twice	4.2.5
Alarm Volume	ALARM SILENCE button (press and hold for 3 seconds before turning knob)	4.2.6
Alarm Silence Duration	ALARM SILENCE button (press and hold; turn knob within 3 seconds)	4.2.7
Configuration Menu	UPPER/LOWER ALARM LIMIT buttons simultaneously	4.2.8

Note: To change neonate default limits, enter the neonatal mode from configuration mode steady state by pressing the NEW PATIENT/NEONATAL button twice within 2 seconds. Change the desired limit using the same method as adult default limits.

When an SpO₂ or pulse rate default limit has been changed, a decimal point will appear after the displayed limit until the configuration mode is exited.

4.2.1 Adult/Neonatal Mode Default

The mode (adult or neonatal) that the monitor is in when exiting the configuration mode, becomes the power-on default.

To change from a power-on default of adult mode to a power-on default of neonatal mode, enter the configuration mode steady state. Press the NEW PATIENT/NEONATAL button twice within 2 seconds and then power-down by pressing the ON/STANDBY button.

4.2.2 Default SpO₂ Upper Alarm Limit

1. From the configuration mode steady state, press and release the UPPER ALARM LIMIT button. The current default value is displayed in the SpO₂% display. Dashes appear in the PULSE RATE display (the upper horizontal segments of the display), indicating that the monitor is in the “set SpO₂ upper alarm limit” mode.
2. To change the upper alarm limit value, rotate the knob on top of the monitor. You cannot decrease the value lower than the current SpO₂ lower alarm limit default setting. The SpO₂ upper alarm limit cannot be set higher than 100.
3. Return to configuration mode steady state.

Note: If you press the LOWER ALARM LIMIT button before the 3-second timeout, you can then change the SpO₂ lower alarm limit default. If you press the UPPER ALARM LIMIT button, you can then change the pulse rate upper alarm limit default. This method can also be used while setting the other default alarm limits.

4.2.3 Default SpO₂ Lower Alarm Limit

1. From the configuration mode steady state, press and release the LOWER ALARM LIMIT button. The current default value is displayed in the SpO₂% display.
2. To change the lower alarm limit default value, rotate the knob on top of the monitor. You cannot increase the value higher than the current SpO₂ upper alarm limit setting. The SpO₂ default lower alarm limit cannot be set lower than 80.
3. Return to configuration mode steady state.

4.2.4 Default Pulse Rate Upper Alarm Limit

1. From the configuration mode steady state, press the UPPER ALARM LIMIT button twice within 3 seconds. The current default value is displayed in the PULSE RATE display. Dashes appear in the SpO₂% display (the upper horizontal segments of the display), indicating that the monitor is in the “set pulse rate upper alarm limit” mode.
2. To change the upper alarm limit default value, rotate the knob on top of the monitor. You cannot decrease the value lower than the current pulse rate lower alarm limit default setting. The pulse rate default upper alarm limit cannot be set higher than 250.
3. Return to configuration mode steady state.

4.2.5 Default Pulse Rate Lower Alarm Limit

1. From the configuration mode steady state, press the LOWER ALARM LIMIT button twice within 3 seconds. The current default value is displayed in the PULSE RATE display.
2. To change the lower alarm limit value, rotate the knob CW to increase, or CCW to decrease. You cannot increase the value higher than the current pulse rate upper limit setting. The pulse rate lower alarm limit cannot be set lower than 30.
3. Return to configuration mode steady state.

4.2.6 Default Alarm Volume

Perform the following steps to adjust the default alarm volume:

1. From the configuration mode steady state, press and hold the AUDIBLE ALARM OFF button. After 3 seconds, a continuous tone at the current volume setting is emitted. "VOL" is displayed in the PULSE RATE display, and the current default alarm setting (a number from 1 to 10) is displayed in the SpO₂% display.
2. While continuing to hold the AUDIBLE ALARM OFF button, turn the control knob on the top of the monitor CW to increase the default volume, CCW to decrease the default volume.
3. Release the AUDIBLE ALARM OFF button and the monitor returns to the configuration mode steady state.

4.2.7 Default Alarm Silence Duration

The default alarm silence duration may also be adjusted while in the configuration mode. To do so:

1. From the configuration mode steady state, press and hold the AUDIBLE ALARM OFF button for 3 seconds or less. The current default setting for the alarm silence duration appears in the PULSE RATE display. The SpO₂% display indicates "CFG", while the AUXILIARY display indicates "SEC" (seconds).

Note: Pressing the AUDIBLE ALARM OFF button for more than 3 seconds without turning the knob, causes the N-3000 to enter the "Default Alarm Volume" mode as described in paragraph 4.2.6.

2. Use the control knob on the top of the N-3000 to adjust the default alarm silence duration. Alarm silence duration choices are 30 SEC, 60 SEC, 90 SEC, and 120 SEC.

4.2.8 Configuration Menu

The configuration menu allows you to configure the functions listed in Table 4-2. After accessing a menu item by pressing the UPPER ALARM LIMIT button, if the knob is not turned and no button is pressed for a period of time equal to the “timeout” as listed in the table, you will automatically return to the configuration menu steady state. The last setting displayed for the menu item will become the default setting.

Table 4-2: Configuration Menu

Menu Number	Configurable Setting	Paragraph Described	Timeout
0	Pulse tone volume	4.2.8.1	3 seconds
1	UIF software version report	4.2.8.2	10 seconds
2	SpO ₂ software version report	4.2.8.3	10 seconds
3	Set baud rate	4.2.8.4	3 seconds
4	Trend type	4.2.8.5	3 seconds
5	Reset to factory defaults	4.2.8.6	N/A

To access the configuration menu from the configuration mode steady state, press the UPPER and LOWER ALARM LIMIT buttons simultaneously. The SpO₂% display indicates the menu number (0 through 5) and the PATIENT MOTION indicator is illuminated to indicate the monitor is in the configuration menu steady state.

Rotate the knob on top of the N-3000 to access the desired menu number. Press the UPPER ALARM LIMIT button to configure the displayed item, using the procedures listed in paragraphs 4.2.8.1 through 4.2.8.6.

To exit the configuration menu steady state and return to the configuration mode steady state, press the LOWER ALARM LIMIT button or, if there is no knob or button activity for 15 seconds, you will automatically return to the configuration mode steady state. You may also exit by turning the monitor off.

4.2.8.1 Pulse Tone Volume

Menu item number “0” allows you to determine the default volume (1 through 10) for the pulse tone.

1. From the configuration menu steady state, rotate the knob until “0” is displayed in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. The current default pulse tone volume setting is displayed in the PULSE RATE display. An audio tone sounds at the current volume setting. Rotate the knob CW or CCW to display the desired power-on default volume level (1 through 10).
3. Press the LOWER ALARM LIMIT BUTTON to return to the configuration menu steady state.

4.2.8.2 UIF Software Version Report

1. From the configuration menu steady state, rotate the knob until “1” is displayed in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. The UIF software version number is the left-most digit in the SpO₂% display. The next two digits in the SpO₂% display represent the major software revision number. The minor software revision number is displayed in the PULSE RATE display. Press the LOWER ALARM LIMIT BUTTON to return to the configuration menu steady state.

4.2.8.3 SpO₂ Software Version Report

1. From the configuration menu steady state, rotate the knob until “2” is displayed in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. The SpO₂ software version number is the left-most digit in the SpO₂% display. The next two digits in the SpO₂% display represent the major software revision number. The minor software revision number is displayed in the PULSE RATE display. Press the LOWER ALARM LIMIT BUTTON to return to the configuration menu steady state.

4.2.8.4 Set Serial Port Baud Rate

1. From the configuration menu steady state, rotate the knob until “3” is displayed in the SpO₂% display. Press the UPPER ALARM LIMIT button.

Note: Baud rates should not exceed 19,200 in RS-232 mode (use EIA-422 mode). Refer to paragraph 6.5.1 to change the communication mode settings.
2. The current baud rate, in thousands, is displayed in the PULSE RATE display. To change the default baud rate setting, rotate the knob until the desired setting is displayed.
3. Press the LOWER ALARM LIMIT button to return to the configuration menu steady state.

4.2.8.5 Trend Type

Menu item number 4 allows you to select “5”, “10” or “20” (displayed in the SpO₂% display) as the default trend format. Selecting “20” causes patient trend data to be recorded every 20 seconds. Each patient parameter value will be both the maximum and minimum data for each parameter during the sample period. Data is stored for the most recent 24 hours of patient monitoring. This selection is described as “Format 2” in the N-3000 operator’s manual.

Selecting “10” causes patient trend data to be recorded every 10 seconds. Each patient parameter value will be the average of all data samples for each parameter during the sample period. Data is stored for the most recent 24 hours of patient monitoring. This selection is described as “Format 1” in the N-3000 operator’s manual.

Selecting “5” causes patient trend data to be recorded every 5 seconds. Each patient parameter value will be the most recent data sample for each parameter during the sample period. Data is stored for the most recent 12 hours of patient monitoring. This selection is described as “Format 3” in the N-3000 operator’s manual.

1. From the configuration menu steady state, rotate the knob until “4” is displayed in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. “5”, “10” or “20” is displayed in the PULSE RATE display. Rotate the knob to display the desired default trend type.
3. Press the LOWER ALARM LIMIT BUTTON to return to the configuration menu steady state.

4.2.8.6 Reset to Factory Defaults

Menu item number 5 allows you to reset all default settings to the original factory settings as listed in paragraph 9.6, “Factory Default Settings,” of the *Specifications* section.

1. From the configuration menu steady state, rotate the knob until “5” is displayed in the SpO₂% display.
2. Press the UPPER ALARM LIMIT button to reset to factory defaults. Three beeps indicate that all configurable power-on default parameters, except latching alarms enable and alarm silence reminder enable, are now set to their factory default values. You are automatically returned to the configuration menu steady state.

4.3 SERVICE MODE

The service mode allows the technician to go through a series of tests to determine monitor functionality and to access the error log report.

The service modes cannot be accessed by the N-3000 while it is stacked with an active N-3100. If operating in the stacked configuration, disconnect the N-3000 from the N-3100 or turn the N-3100 off before entering the service mode.

Use the following procedures to place the monitor into the service mode:

1. If the monitor is on, turn it off.
2. While simultaneously holding down the UPPER and LOWER ALARM LIMIT buttons and the PRINT button, press and release the ON/STANDBY button. Continue to press and hold the UPPER and LOWER ALARM LIMIT and PRINT buttons while the monitor performs the power-on self-test.
3. When “SEr” begins flashing in the AUXILIARY display, release the UPPER and LOWER ALARM LIMIT and PRINT buttons.

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4. Press the PRINT button. You must press this button within 15 seconds or the monitor will turn off automatically. You are now in service mode steady state.

Note: Failure errors (refer to *Troubleshooting* section for an explanation of failure errors and error codes) may be encountered by the N-3000 upon entering the service mode. The N-3000 will automatically access the menu item used to correct this situation.

If a user-correctable error code (a code beginning with “0”) is displayed while in the service mode, press the LOWER ALARM LIMIT button to clear the error.

- “SEr” stops flashing and is continuously displayed.
- The number “1” is indicated in the SpO₂% display.
- The PATIENT MOTION indicator is lit, indicating that you are in the service mode steady state, with access to the main menu as indicated in Table 4-3.

MOTION

5. Use the knob to move from one main menu item to the next.

While in service mode, the UPPER and LOWER ALARM LIMIT buttons are used as enter and exit buttons, respectively. You must press the UPPER ALARM LIMIT button to select a main menu item and move to the submenu level.

6. When you have scrolled to the desired menu item, press the UPPER ALARM LIMIT button. The PATIENT MOTION indicator goes out and the PULSE SEARCH indicator illuminates.

PULSE SEARCH

This indicates that you are now in a submenu of the selected main menu item. Use the knob to move from one submenu item to the next. Not all menu items have submenu selections.

7. To return to the service mode steady state from a menu item, press the LOWER ALARM LIMIT button. (Menu item 3, Button Test, is an exception; it is exited by rotating the knob.)
8. To exit the service mode, power-down the monitor by pressing the ON/STANDBY button. The N-3000 is automatically powered down if no action is taken for approximately 5 minutes.

Main menu items available from the service mode steady state are discussed in numerical order as indicated in Table 4-3.

Section 4: Configuration Mode, Service Mode, and Alarm Active Function**Table 4-3: Service Mode Steady State - Main Menu**

Menu No.	Type of Report/Test	Paragraph Described
1	Software Version Report	4.3.1
2	Knob and Lamp Test	4.3.2
3	Button Test	4.3.3
4	Speaker Test	4.3.4
5	Internal Configuration Code (ICC) Report	4.3.5
6	Total Operating Hours Report	4.3.6
7	Error Log Record 1	4.3.7
8	Error Log Record 2	4.3.7
9	Error Log Record 3	4.3.7
10	Error Log Record 4	4.3.7
11	Error Log Record 5	4.3.7
12	Error Log Record 6	4.3.7
13	Error Log Record 7	4.3.7
14	Error Log Record 8	4.3.7
15	Error Log Record 9	4.3.7
16	Error Log Record 10	4.3.7
17	Instrument Identification (IID) Report	4.3.8
18	Power Management and Battery Status	4.3.9
19	Persistent Time Sense Report	4.3.10
20	Reset to Factory Defaults	4.3.11
21	Initial Cluster Instrument Number Report	4.3.12
22	Enable/Disable Latching Alarms	4.3.13
23	Enable/Disable Alarm Silence Reminder	4.3.14
25	Dump EEPROM Data	4.3.15
28	Enable/Disable Battery Charge Circuit	4.3.16
29	Instrument Compatibility Report	4.3.17
30	SpO ₂ RCAL Report	4.3.18
31	SpO ₂ IR and Red Offset Report	4.3.19
32	SpO ₂ Corrected IR and Red Signals Report	4.3.20
33	SpO ₂ IR LED Drive Test	4.3.21
34	SpO ₂ Red LED Drive Test	4.3.22
35	SpO ₂ DM-Gain Test	4.3.23
36	SpO ₂ P-Gain Test	4.3.24
37	Set SpO ₂ Analog Test Mode	4.3.25
38	SpO ₂ A/D-Cal Line Test	4.3.26
39	SpO ₂ Enable Automatic Operation	4.3.27
60	Set Serial Port Baud Rate	4.3.28
61	Serial Port Loop Back Test	4.3.29
62	Serial Port Transmit Test	4.3.30
70	Nellcor Puritan Bennett Internal Test - <i>DO NOT USE</i>	

4.3.1 Menu Item 1: Software Version Report

This report identifies the software versions of the UIF and SpO₂ modules.

1. From the service mode steady state, select menu item 1 by rotating the *Nellcor Puritan Bennett* knob until “1” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. A “1.0” appears in the SpO₂% display.

The UIF software version number is the left-most digit in the PULSE RATE display. The next two digits in the PULSE RATE display represent the major software revision number. The minor software revision number is displayed in the AUXILIARY display.

2. Rotate the knob to change the number in the SpO₂% display to “1.1”. The SpO₂ software version number is the left-most digit in the PULSE RATE display. The next two digits in the PULSE RATE display represent the major software revision number. The minor software revision number is displayed in the AUXILIARY display.
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.2 Menu Item 2: Knob and Lamp Test

This test verifies that indicators, front-panel lamps, and the control knob are functional.

1. From the service mode steady state, select menu item 2 by rotating the knob until “2” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. All indicators light.
2. Rotate the knob CW to light each display segment, decimal, indicator, and blip bar in a firefly pattern to verify that each lamp works.

Note: The POWER-ON indicator is not tested with this procedure. It can be verified by turning the monitor on and off. The BATTERY CHARGING indicator is also not tested.

3. Rotate the knob CCW to reverse the firefly pattern. Knob functionality is verified by the even movement through the firefly pattern as the knob is turned.
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.3 Menu Item 3: Button Test

This test verifies proper operation of individual buttons and button combinations.

1. From the service mode steady state, select menu item 3 by rotating the *Nellcor Puritan Bennett* knob until “3” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. A “0” appears in the PULSE RATE display.

2. Press each of the buttons and button combinations listed below. The corresponding number appears in the PULSE RATE display to indicate that these buttons and button combinations are functioning correctly.

Press the following button and/or button combinations:	Displayed number:
None pressed	0
Audible alarm off	1
New patient/neonatal (rear panel)	2
Upper alarm limit	3
Lower alarm limit	4
Print	5
Upper and lower alarm limits, simultaneously	6
Upper/lower limits and print, simultaneously	7
Upper limit and audible alarm off, simultaneously	8
Lower limit and audible alarm off, simultaneously	9
Any combination not listed above	10

3. Rotate the knob CW or CCW to return to the service mode steady state.

4.3.4 Menu Item 4: Speaker Test

This test verifies that the volume control is functional and determines whether or not there are any discontinuities or saturation conditions in the audible output.

1. From the service mode steady state, select menu item 4 by rotating the knob until "4" appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. A "1" appears in the PULSE RATE display and a low-level audible tone heard.
2. Rotate the control knob CW. As the number in the PULSE RATE display increases from 0 to 254, the volume will correspondingly increase.
3. Rotate the control knob CCW to decrease the volume.
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.5 Menu Item 5: Internal Configuration Code (ICC) Report

This menu item verifies whether the current monitor configuration is the desired configuration. The ICC is the hexadecimal representation of the instrument hardware configuration derived by the UIF processor through internal examination of the modules and software present in the N-3000.

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1. From the service mode steady state, select menu item 5 by rotating the knob until “5” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The ICC value appears as the two right-most digits in the PULSE RATE display. The monitor’s configuration is represented by one of the following values:

ICC Value	Monitor Configuration
03	SpO ₂ only, with serial port
07	SpO ₂ and ECG only, with serial port
0F	SpO ₂ , ECG and respiration, with serial port
12	SpO ₂ only, with wired network interface
16	SpO ₂ and ECG only, with wired network interface
1E	SpO ₂ , ECG and respiration, with wired network interface
FF	Invalid configuration

If the displayed ICC value differs from the value stored in the EEPROM, then the displayed value will flash.

2. If the displayed value is flashing, press the UPPER ALARM LIMIT button to save the value as the default.
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.6 Menu Item 6: Total Operating Hours Report

This report displays the total number of operating hours logged by the unit since it was produced.

1. From the service mode steady state, select menu item 6 by rotating the knob until “6” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The total number of operating hours is displayed in the SpO₂% and PULSE RATE displays. Possible values are from 0 to 999,999 hours.
2. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.7 Menu Items 7-16: Error Log Record Report

This report provides information regarding the last ten error codes recorded by the monitor, the number of occurrences of that particular error, and the number of operating hours at the last time the error occurred. The error log has ten entries (menu items 7-16), as indicated below. Refer to Section 5, *Troubleshooting*, and the Appendix for an explanation of error codes.

The following procedure is for Error Log Record 1 (menu item 7). Use the same procedure to access Error Log Records 2 through 10 (menu items 8 through 16).

1. From the service mode steady state, select menu item 7 by rotating the knob until “7” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The number “7.0” appears in the SpO₂% display.

2. Read the error code in the PULSE RATE display. A value of “000” indicates that the menu item contains no error code. If dashes are displayed, the error log contents cannot be determined.
3. Rotate the control knob CW to display “7.1” in the SpO₂% display.
4. Read the number of occurrences of this particular error code in the PULSE RATE display. If “256” is displayed, there have been 256 or more occurrences.
5. Continue to rotate the control knob CW. The total number of operating hours when the last instance of the error occurred is displayed in the SpO₂% and PULSE RATE displays.
6. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.8 Menu Item 17: Instrument Identification (IID) Report

This report displays a hexadecimal number corresponding to the instrument identifier. This number should agree with the address label on the outside of the instrument. However, the label and the internal value may disagree if the monitor UIF module was replaced and the external label was not changed.

1. From the service mode steady state, select menu item 17 by rotating the knob until “17” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. A hexadecimal number appears across the entire monitor display, with an “H” in the last (far right) position.
2. Verify that this number agrees with the number on the monitor external label. If the number does not agree, the number on the external label should be changed to agree with the displayed number.
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.9 Menu Item 18: Power Status

This test allows you to determine battery conditions.

1. From the service mode steady state, select menu item 18 by rotating the knob until “18” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The number “18.0” appears in the SpO₂% display. The number shown in the PULSE RATE display is the lead-acid battery voltage to the nearest tenth of a volt.
2. Rotate the control knob CW until “18.1” appears in the SpO₂% display. The number shown in the PULSE RATE display is the charge bus voltage to the nearest tenth of a volt.
3. Rotate the control knob CW until “18.2” appears in the SpO₂% display. The number shown in the PULSE RATE display is the backup lithium battery voltage to the nearest tenth of a volt.

Note: The control knob can be rotated until “18.3” appears in the SpO₂% display. However, the number shown in the PULSE RATE display has no meaning and can be ignored.

4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.10 Menu Item 19: Persistent Time Sense Report

This report allows you to determine if the internal persistent time circuit is keeping time correctly.

1. From the service mode steady state, select menu item 19 by rotating the knob until “19” appears in the SpO₂% display.
2. Press the UPPER ALARM LIMIT button. The persistent time in seconds is displayed in the SpO₂% and PULSE RATE displays. For example, “001 688” indicates that the monitor has been powered on for 1,688 seconds = 28 minutes, 8 seconds. Make a note of the displayed time.

If the display reads “999 999” this indicates that persistent time is greater than or equal to 999,999 seconds. If dashes are displayed, the contents of the memory of the persistent time circuit are lost. This can occur when the backup lithium battery has been replaced.

3. Using a watch or other timepiece, wait 3 minutes. Subtract the first figure you noted from the figure now displayed on the N-3000. The difference should equal approximately 3 minutes (180 seconds).
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.11 Menu Item 20: Reset to Factory Defaults

This function allows you to reset the monitor to the Nellcor Puritan Bennett factory default settings (see the *Specifications* section of this manual).

From the service mode steady state, select menu item 20. As soon as you press the UPPER ALARM LIMIT button, the default settings are reset. Any preset configurable alarms are now lost. When the default settings are reset, the monitor will beep three times and automatically return to the service mode steady state. If the reset was not successful, an error code will be displayed.

4.3.12 Menu Item 21: Initial Cluster Instrument Number Report

This report displays a hexadecimal number corresponding to the initial internal stack address when the instrument is being used in a stack configuration with an address conflict. Such a conflict may occur when identical instrument types (for example, two N-3100s) are in the same stack.

1. From the service mode steady state, select menu item 21 by rotating the knob until “21” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The two left-most digits in the PULSE RATE display are the hexadecimal representation of the cluster instrument number. “H” (for hexadecimal) is displayed as the right-most digit of the PULSE RATE display.
2. If the displayed value is different than the EEPROM value, the display will flash. Rotate the knob to adjust the cluster instrument number to the desired value.
3. Press the UPPER ALARM LIMIT button to accept the displayed value as the default value. The display stops flashing.
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.13 Menu Item 22: Enable/Disable Latching Alarms

This function allows you to disable or enable the latching alarm feature. The Nellcor Puritan Bennett factory default setting is latching alarm disabled.

1. From the service mode steady state, select menu item 22 by rotating the knob until “22” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. Observe the enable/disable latching alarm setting of “OFF” or “ON” in the PULSE RATE display.

OFF = latching alarm disabled
ON = latching alarm enabled
3. To change the enable/disable latching alarm setting, rotate the knob until the desired setting is displayed (flashing).
4. Press the UPPER ALARM LIMIT button to store the default setting.
5. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.14 Menu Item 23: Enable/Disable Alarm Silence Reminder

This function allows you to disable or enable the alarm silence reminder feature. The Nellcor Puritan Bennett factory default setting is alarm silence reminder enabled.

1. From the service mode steady state, select menu item 23 by rotating the knob until “23” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. Observe the alarm silence reminder setting of “OFF” or “ON” in the PULSE RATE display.

OFF = alarm silence reminder disabled
ON = alarm silence reminder enabled
3. To change the alarm silence reminder setting, rotate the knob until the desired setting is displayed (flashing).
4. Press the UPPER ALARM LIMIT button to store the default setting.
5. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.15 Menu Item 25: Dump EEPROM Data

This function allows you to dump the entire contents of the EEPROM to a serial data capture device. This data may then be transmitted to Nellcor Puritan Bennett to assist in diagnosing the condition of the instrument.

Note: The N-3000 must be operating from AC power to perform this menu item.

1. Turn the N-3000 off.
2. Connect the N-3000 to a PC through the serial port.

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3. Execute your communication software application. Port settings should be set as indicated below:

Baud Rate	19,200 (or equivalent to N-3000 setting as determined by using menu item 60)
Parity	N
Data Bits	8
Stop Bits	1

4. Power-on the N-3000 and place it in the service mode steady state.
5. Select menu item 25 by rotating the knob until “25” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. “EE” will be displayed in the PULSE RATE display.
6. Press the PRINT button to transmit the contents of the EEPROM memory out of the serial port.
7. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.16 Menu Item 28: Enable/Disable Battery Charge Circuit

This test allows you to turn the battery charging circuit on or off.

1. From the service mode steady state, select menu item 28 by rotating the knob until “28” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
2. Observe the battery charging circuit setting of “OFF” or “ON” in the PULSE RATE display.

OFF = battery charging circuit disabled
ON = battery charging circuit enabled
3. To enable or disable the battery charge circuit, rotate the knob until the desired setting is displayed (flashing). Press the UPPER ALARM LIMIT button.
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.17 Menu Item 29: Instrument Compatibility Report

This function allows you to determine the cause of an “instruments not compatible” error message.

1. From the service mode steady state, select menu item 29 by rotating the knob until “29” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The number “29.0” appears in the SpO₂% display. The number in the PULSE RATE display is the sensorbus protocol version and revision number of the N-3000.
2. Rotate the knob until “29.1” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The number in the PULSE RATE display is the multicast version and revision number of the N-3000.
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.18 Menu Item 30: SpO₂ RCAL Report

This function allows you to check the sensor RCAL value readings.

1. Connect the SRC-2 tester or a compatible sensor to the N-3000.
2. Select menu item 30 by rotating the knob until “30” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
3. Read the RCAL standard representation of the nominal sensor resistance in the PULSE RATE display.
4. If connected to an SRC-2 tester, set the SRC-2 RCAL/Mode switch to 63. The RCAL value “63” is displayed in the PULSE RATE display. Set the SRC-2 RCAL/Mode switch to 64. The RCAL value “64” is displayed in the PULSE RATE display.
5. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.19 Menu Item 31: SpO₂ IR and Red Offset Report

This function allows you to validate the operation of the SpO₂ module. The values represent the DC voltage offset for the current amplifier gain when the amplifier inputs are zeroed.

1. Connect the sensor cable and SRC-2 to the N-3000.
2. Set the SRC-2 as follows:

<u>SWITCH</u>	<u>POSITION</u>
RATE	38
LIGHT	LOW
MODULATION	OFF
MODE	LOC/RCAL 63

3. From the service mode steady state, select menu item 31 by rotating the knob until “31” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The SpO₂ IR offset appears in the SpO₂% display, and the SpO₂ red offset appears in the PULSE RATE display. The values are displayed in millivolts.
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.20 Menu Item 32: SpO₂ Corrected IR and Red Signals Report

This function allows you to validate the operation of the SpO₂ module. The values represent the outputs of the IR and red sensor channels after the amplifier offset values have been applied.

1. Connect the sensor to the N-3000.
2. Verify that the SpO₂ module is set for automatic operation using menu item 39 (paragraph 4.3.27).
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

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4. From the service mode steady state, select menu item 32 by rotating the knob until “32” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button. The SpO₂ corrected IR output signal is displayed in the SpO₂% display in hundredths of volts. The SpO₂ corrected red output signal is displayed in the PULSE RATE display in hundredths of volts.
5. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.21 Menu Item 33: SpO₂ IR LED Drive Test

This function allows you to validate sensors and/or the operation of the SpO₂ module.

1. Connect the sensor to the N-3000.
2. Verify that the SpO₂ module is set for automatic operation using menu item 39 (paragraph 4.3.27).
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.
4. From the service mode steady state, select menu item 33 by rotating the knob until “33” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
5. The SpO₂ IR drive value (between 0–255) is displayed in the PULSE RATE display.
6. To adjust the drive value, rotate the *Nellcor Puritan Bennett* knob. The PULSE RATE display will flash. Pressing the UPPER ALARM LIMIT button will set the displayed value in the SpO₂ module, which will cease its automatic operation. The PULSE RATE display will stop flashing.
7. Press and hold the PRINT button to display the SpO₂ corrected IR and red output signals as described in menu item 32. Release the PRINT button.
8. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.22 Menu Item 34: SpO₂ Red LED Drive Test

This function allows you to validate sensors and/or the operation of the SpO₂ module.

1. Connect the sensor to the N-3000.
2. Verify that the SpO₂ module is set for automatic operation using menu item 39 (paragraph 4.3.27).
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.
4. From the service mode steady state, select menu item 34 by rotating the knob until “34” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
5. The SpO₂ red LED drive value (between 0-255) is displayed in the PULSE RATE display.

6. To adjust the drive value, rotate the knob. The PULSE RATE display will flash. Pressing the UPPER ALARM LIMIT button will set the displayed value in the SpO₂ module, which will cease its automatic operation. The PULSE RATE display will stop flashing.
7. Press and hold the PRINT button to display the SpO₂ corrected IR and red output signals as described in menu item 32. Release the PRINT button.
8. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.23 Menu Item 35: SpO₂ DM-Gain Test

This function allows you to validate sensors and/or the operation of the SpO₂ module.

1. Connect the sensor to the N-3000.
2. Verify that the SpO₂ module is set for automatic operation using menu item 39 (paragraph 4.3.27).
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.
4. From the service mode steady state, select menu item 35 by rotating the knob until “35” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
5. The SpO₂ demodulator gain value (from 0 to 6) is displayed in the PULSE RATE display.
6. To adjust the gain, rotate the knob. The PULSE RATE display will flash. Pressing the UPPER ALARM LIMIT button will set the displayed value in the SpO₂ module, which will cease its automatic operation. The PULSE RATE display will stop flashing.
7. Press and hold the PRINT button to display the SpO₂ corrected IR and red output signals as described in menu item 32. Release the PRINT button.
8. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.24 Menu Item 36: SpO₂ P-Gain Test

This function allows you to validate sensors and/or the operation of the SpO₂ module.

1. Connect the sensor to the N-3000.
2. Verify that the SpO₂ module is set for automatic operation using menu item 39 (paragraph 4.3.27).
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.
4. From the service mode steady state, select menu item 36 by rotating the knob until “36” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.

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5. The SpO₂ preamp gain (from 0 to 3) is displayed in the PULSE RATE display.
6. To adjust the gain value, rotate the knob. The PULSE RATE display will flash. Pressing the UPPER ALARM LIMIT button will set the displayed value in the SpO₂ module, which will cease its automatic operation. The PULSE RATE display will stop flashing.
7. Press and hold the PRINT button to display the SpO₂ corrected IR and red output signals as described in menu item 32. Release the PRINT button.
8. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.25 Menu Item 37: Set SpO₂ Analog Test Mode

This function allows you to validate sensors and/or the operation of the SpO₂ module.

1. Connect the sensor to the N-3000.
2. From the service mode steady state, select menu item 37 by rotating the knob until “37” appears in the SpO₂ % display. Press the UPPER ALARM LIMIT button.
3. The test mode setting of “0” (normal operation) is displayed in the PULSE RATE display. “SEr” is displayed in the AUXILIARY display and “37” is displayed in the SpO₂% digital display.

4. Rotate the knob to select other settings.

1 = “zero” setting

2 = “system test” setting

If the displayed value is different from the current SpO₂ value, the display will flash.

Pressing the UPPER ALARM LIMIT button will set the displayed value in the SpO₂ module, which will cease its automatic operation.

5. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.26 Menu Item 38: SpO₂ A/D-Cal Line Test

This function allows you to verify calibration of the SpO₂ A/D converter.

1. From the service mode steady state, select menu item 38 by rotating the knob until “38” appears in the SpO₂ % display. Press the UPPER ALARM LIMIT button.

2. Observe the PULSE RATE display. The possible values 0, 1, 2, or 3 indicate the following status
 - “0” Indicates that both A/D converters are undergoing self-calibration, which will take approximately 3 seconds. A value of “0” after the 3-second period indicates that both converters have failed self-calibration.
 - “1” Indicates that the IR A/D converter has completed self-calibration and the red A/D is still undergoing self-calibration or has failed self-calibration.
 - “2” Indicates that the red A/D converter has completed self-calibration and the IR A/D is still undergoing self-calibration or has failed self-calibration.
 - “3” Indicates that both converters have completed self-calibration.
3. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.27 Menu Item 39: SpO₂ Enable Automatic Operation

This function allows you to reset and confirm that the SpO₂ module is operating in the automatic mode.

1. Connect the sensor to the N-3000.
2. From the service mode steady state, select menu item 39 by rotating the knob until “39” appears in the SpO₂ % display. Press the UPPER ALARM LIMIT button.
3. Observe the SpO₂ automatic operation setting of “OFF” or “ON” in the PULSE RATE display.

OFF = SpO₂ module is not in automatic operation
ON = SpO₂ module is in automatic operation
4. Rotate the knob to change the display and turn automatic operation ON or OFF.
5. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.28 Menu Item 60: Set Serial Port Baud Rate

This function allows you to set the default serial port baud rate.

1. From the service mode steady state, select menu item 60 by rotating the knob until “60” appears in the SpO₂ % display. Press the UPPER ALARM LIMIT button.
2. The current baud rate, in hundreds, is displayed in the PULSE RATE display. To change the default baud rate setting, rotate the knob until the desired setting is displayed.

Note: When connected to a PC in the RS-232 format, a baud rate above 19,200 should not be used.
3. Press the UPPER ALARM LIMIT button to store the default setting.

Section 4: Configuration Mode, Service Mode, and Alarm Active Function

4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.29 Menu Item 61: Serial Port Loop Back Test

This test verifies that, when the N-3000 is connected to a PC through the N-3000 serial port, the serial port receive hardware is functional.

Note: The N-3000 must be operating from AC power to perform this menu item.

1. Turn the N-3000 off.
2. Connect the N-3000 to a PC through the serial port.
3. Execute your communication software application. Port settings should be set as indicated below:

Baud Rate	19200 (or as set using menu item 60)
Parity	N
Data Bits	8
Stop Bits	1

4. Turn on the N-3000 and place it in the service mode.
5. Select menu item 61 by rotating the knob until “61” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
6. Type any characters on your PC keyboard and verify that the characters are echoed on the PC screen. This confirms that data received on the serial port receive line is transmitted on the transmit data line.
7. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

4.3.30 Menu Item 62: Serial Port Transmit Test

This test verifies that, when the N-3000 is connected to a PC through the N-3000 serial port, the serial port transmit hardware is functional.

Note: The N-3000 must be operating from AC power to perform this menu item.

1. Perform steps 1 through 4 as indicated in paragraph 4.3.29, menu item 61.
2. Select menu item 62 by rotating the knob until “62” appears in the SpO₂% display. Press the UPPER ALARM LIMIT button.
3. Verify that a fixed pattern of bytes (0 through 255) is repeatedly sent on the transmit data line. The characters are repeatedly sent on the transmit data line when menu item 62 is selected.
4. Press the LOWER ALARM LIMIT button to return to the service mode steady state.

Caution: Menu items 70 and above are for factory purposes only. Adjustment of menu items 70 and above by other than qualified factory personnel may cause the N-3000 to malfunction.

4.4 ALARM ACTIVE FUNCTION

The N-3000 alarm active function allows low, medium, or high priority alarms to be monitored from a remote location via the N-3000 serial port. Alarm monitoring also applies to an attached, active N-3100. This function is automatically enabled during the power-on cycle.

Pin 6 is open when no alarms are active. Alarm activity results in pin 6 shorting to ground. The pin will remain shorted to ground as long as the alarm is sounding.

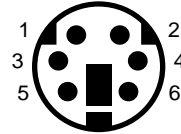


Figure 4-1: Serial Port Pin Locations

If voltage levels of ± 7 volts on pin 1 are desired for remote alarm monitoring (while in RS-232 mode), short together the DSR (pin 2) and TXD (pin 3) lines of the communication cable. Once the alarm active function has been enabled during power-on, an alarm will toggle the DTR line pin 1 from a logic LOW of -7 volts to a HIGH of +7 volts. As long as the alarm is sounding, this line will remain HIGH. When the alarm is silenced, or becomes inactive, the line will return to its LOW logic level.

If a continuous 3.3 volt signal on pin 6 is desired (as when using the *Nellcor Puritan Bennett* SOC-3 adapter), change the dip switch settings on the Communications PCB as instructed in paragraph 6.5.1.

SECTION 5: TROUBLESHOOTING

- 5.1 Introduction
 - 5.2 How to Use this Section
 - 5.3 Who Should Perform Repairs
 - 5.4 Replacement Level Supported
 - 5.5 Obtaining Replacement Parts
 - 5.6 Troubleshooting Guide
-

5.1 INTRODUCTION

This section explains how to troubleshoot the N-3000 if problems arise. Tables are supplied that list possible monitor difficulties, along with probable causes, and recommended actions to correct the difficulty.

5.2 HOW TO USE THIS SECTION

Use this section in conjunction with Section 3, *Performance Verification*, and Section 7, *Spare Parts*. To remove and replace a part you suspect is defective, follow the instructions in Section 6, *Disassembly Guide*. The circuit analysis section in the Technical Supplement offers information on how the monitor functions.

5.3 WHO SHOULD PERFORM REPAIRS

Only qualified service personnel should open the monitor housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.

5.4 REPLACEMENT LEVEL SUPPORTED

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in Section 6, *Disassembly Guide*, to replace the PCB with a known good PCB. Check to see if the trouble symptom disappears and that the monitor passes all performance tests. If the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

5.5 OBTAINING REPLACEMENT PARTS

Nellcor Puritan Bennett Technical Services provides technical assistance information and replacement parts. To obtain replacement parts, contact Nellcor Puritan Bennett or your local Nellcor Puritan Bennett representative. Refer to parts by the part names and part numbers listed in Section 7, *Spare Parts*.

Section 5: Troubleshooting

5.6 TROUBLESHOOTING GUIDE

Problems with the N-3000 are separated into the categories indicated in Table 5-1. Refer to the paragraph indicated for further troubleshooting instructions.

Note: Taking the recommended actions discussed in this section will correct the majority of problems you will encounter. However, problems not covered here can be resolved by calling Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.

Table 5-1: Problem Categories

Problem Area	Refer to Paragraph
1. Power <ul style="list-style-type: none"> • No power-up on AC and/or DC • Fails power-on self-test • Powers down without apparent cause 	5.6.1
2. Error Messages	5.6.2
3. Buttons/Knob <ul style="list-style-type: none"> • Monitor does not respond properly to buttons and/or knob 	5.6.3
4. Display/Alarms <ul style="list-style-type: none"> • Displays do not respond properly • Alarms or other tones do not sound properly or are generated without apparent cause 	5.6.4
5. Operational Performance <ul style="list-style-type: none"> • Displays appear to be operational, but monitor shows no readings • Suspect readings 	5.6.5
6. Stacked Configuration <ul style="list-style-type: none"> • N-3000 operates properly when used alone but not when stacked 	5.6.6
7. Serial Port <ul style="list-style-type: none"> • N-3000 and PC not communicating properly 	5.6.7

All of the categories in Table 5-1 are discussed in the following paragraphs.

5.6.1 Power

Power problems are related to AC and/or DC. Table 5-2 lists recommended actions to power problems.

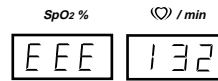
Table 5-2: Power Problems

Condition	Recommended Action
1. BATTERY-IN-USE/BATTERY LOW indicator lights steadily while N-3000 is connected to AC via the external power supply.	<ol style="list-style-type: none">1. Ensure that the SPS power supply is plugged into an operational AC outlet. If it is, and the green indicator light is not lit, replace the power supply.2. If the green SPS indicator is lit, ensure that the power supply is properly plugged into the N-3000.3. Check the fuse. The fuse is located on the lower docking connector as indicated in paragraph 6.3 and Figure 6-3 of the <i>Disassembly Guide</i> section. Replace if necessary.4. Check the ribbon connection from the bottom enclosure to the UIF PCB, as instructed in paragraph 6.5 of the <i>Disassembly Guide</i> section. If the connection is good, replace the UIF PCB.
2. The N-3000 does not operate when disconnected from its external power supply or the power failure alarm sounds when AC power is disconnected.	<ol style="list-style-type: none">1. The battery may be discharged. To recharge the battery, refer to paragraph 3.3.2, Battery Charge. The monitor may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge.2. If the battery fails to hold a charge, replace the battery as indicated in Section 6, <i>Disassembly Guide</i>.
3. BATTERY-IN-USE/BATTERY LOW indicator flashes during DC operation.	There are 15 minutes or less of usable charge left on the N-3000 battery. At this point, if possible, cease use of the N-3000 on battery power, connect it to its external power source and allow it to recharge (approximately 14 hours). The N-3000 may continue to be used while it is recharging.
4. The microprocessor failure alarm sounds and no error code is displayed.	Replace the UIF PCB.

Section 5: Troubleshooting

5.6.2 Error Codes

When there is a problem within the N-3000 monitor, an error code may be displayed on the front panel, as illustrated:



These codes correspond to messages that indicate what part of the monitor is at fault. Actions to take when encountering error codes are listed below. For a more thorough understanding of the error codes, refer to Appendix A.

5.6.2.1 User-Correctable Error Codes

The following error codes can be corrected by the operator:

Error Code Explanation

- | | |
|-----|--|
| 055 | Current user input values (limits, volumes, times) have been lost during an internal reset and the unit has returned to power-on defaults. Reset to desired values if different from power-on defaults. |
| 058 | Alarm and beep volume, audible alarm silence duration and operating mode have returned to power-on defaults due to an internal instrument reset. |
| 081 | Cannot calibrate sensor (possible shorted/open LED or cable). Check sensor and cable connections. Check sensor and cable; replace if necessary. If replacing sensor and/or cable does not fix the problem, remove the N-3000 monitor from service. Use the SpO ₂ diagnostic tests (service mode menu item numbers 31 through 39) to further evaluate the problem. |

5.6.2.2 Failure Error Codes

Failure error codes are those that are displayed by the monitor with a leading digit other than "0". In some cases, these codes can be cleared by simply turning the monitor off and then on again.

Table 5-3 lists the possible failure error codes and the recommended action to take. If the action requires replacement of a PCB, refer to Section 6, *Disassembly Guide*. If the recommended action fails to solve the problem, notify Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative. Refer to the Appendix for a further explanation of the codes.

Table 5-3: N-3000 Failure Error Codes

Error Code	Recommended Action
106	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down the monitor and verify that the UIF PCB ROM (U3) is securely seated in its socket. Turn the monitor on again. 3. If the error code still appears, power down the monitor and replace the UIF PCB.
108, 109, 111, 178	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down the monitor and replace the UIF PCB.
110	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. Use service mode menu item number 18 to evaluate the status of the lithium backup battery. 3. If necessary, power-down the monitor and replace the lithium backup battery. 4. If the error code still appears, power down the monitor and replace the UIF PCB.
151, 175, 176	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down the monitor and verify that the SpO₂ Module ROM is securely seated in the socket. 3. Verify that the SpO₂ Controller PCB is securely seated. 4. Turn the monitor on. If the error code still appears, replace the SpO₂ Controller PCB. 5. If the error code still appears, power-down the monitor and replace the UIF PCB.
159	<ol style="list-style-type: none"> 1. Use the service mode menu item 20 to reset the default values to factory default values as discussed in Section 4, <i>Configuration and Service Modes</i>. 2. If the error code still appears, power-down the monitor and replace the UIF PCB. 3. If the error code still appears, power down the monitor and replace the SpO₂ Controller PCB.
177	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears and the N-3000 is stacked with another instrument, turn all stacked instruments off and then on again.

Section 5: Troubleshooting**Table 5-3: N-3000 Failure Error Codes - Continued**

Error Code	Recommended Action
178, 191	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, use the service mode, menu item 20, to reset the default values to factory default values as discussed in Section 4, <i>Configuration and Service Modes</i>. 3. If the error code still appears, power-down the monitor and replace the UIF PCB.
179	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, verify compatibility of UIF Module SW ROM and SpO₂ Module SW ROM part numbers by using service mode menu item 17. 3. If the numbers are compatible, power-down and verify that the SpO₂ Module ROM is securely seated. 4. Verify that the SpO₂ Controller PCB and SpO₂ module are securely seated. 5. Turn the monitor on. If the error code still appears, replace the SpO₂ Controller PCB. 6. If the error code still appears, power-down the monitor and replace the UIF PCB.
183, 283	Turn the monitor off, then on again.
189	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down the monitor and replace the UIF PCB.
192, 195, 196	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. Use the service mode, menu item 29, to verify the compatibility of your software. 3. If the error code still appears, verify compatibility of the ROMs by calling Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.
203, 206, 211	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down the monitor and replace the SpO₂ Controller PCB.
204, 205	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down the monitor and replace the SpO₂ PCB. 3. If the error code still appears, power down the monitor and replace the SpO₂ Controller PCB.
275, 276	<ol style="list-style-type: none"> 1. Turn the monitor off, then on again. 2. If the error code still appears, power-down and verify that the SpO₂ Controller PCB is securely seated. 3. If the error code still appears, replace the SpO₂ Controller PCB. 4. If the error code still appears, power down the monitor and replace the UIF PCB.

5.6.3 Buttons/Knob

Table 5-4 lists symptoms of problems relating to nonresponsive buttons or the *Nellcor Puritan Bennett* knob and recommended actions. If the action requires replacement of a PCB, refer to Section 6, *Disassembly Guide*.

Table 5-4: Buttons/Knob Problems

Condition	Recommended Action
1. The N-3000 turns on but does not respond to the knob (buttons are operational).	<ol style="list-style-type: none">1. If possible, verify the problem with the service mode, menu item 2, knob and lamp test.2. Verify proper connection between knob and UIF PCB.3. If the condition still persists, replace the UIF PCB.
2. The N-3000 responds to some, but not all buttons.	<ol style="list-style-type: none">1. Verify the problem and identify faulty buttons with the service mode, menu item 3, button test.2. If faulty buttons are AUDIBLE ALARM SILENCE button or NEW PATIENT/NEONATAL button, replace UIF PCB.3. If faulty buttons are on front panel, replace Display PCB. If the buttons still do not work, replace the UIF PCB.
3. The N-3000 turns on but does not respond to either the knob or any of the buttons.	<ol style="list-style-type: none">1. Press the NEW PATIENT/NEONATAL button twice rapidly. If the NEONATAL MODE indicator lights, replace the Display PCB.2. If the NEONATAL MODE indicator does not light, replace the UIF PCB.

Section 5: Troubleshooting

5.6.4 Display/Alarms

Table 5-5 lists symptoms of problems relating to nonfunctioning displays, audible tones or alarms, and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-5: Display/Alarms Problems

Condition	Recommended Action
1. Display values are missing or erratic.	<ol style="list-style-type: none">1. If the sensor is connected, replace the sensor connector assembly.2. If the condition persists, replace the sensor extension cable.3. If the condition does not change, replace the SpO₂ PCB.4. If the condition still persists, replace the UIF PCB.
2. Display segments do not light.	<ol style="list-style-type: none">1. Verify the problem with the service mode menu item 2, knob and lamp test.2. Check the connection between the UIF PCB and the Display PCB.3. If the condition does not change, replace the Display PCB.4. If the condition still persists, replace the UIF PCB.
3. Alarm sounds for no apparent reason.	<ol style="list-style-type: none">1. Moisture or spilled liquids can cause an alarm to sound. Allow the monitor to dry thoroughly before using.2. If the condition persists, replace the UIF PCB.
4. Alarm does not sound.	<ol style="list-style-type: none">1. Verify the problem with the service mode menu item 4, speaker test.2. Replace the speaker as described in Section 6, <i>Disassembly Guide</i>.3. If the condition persists, replace the UIF PCB.

5.6.5 Operational Performance

Table 5-6 lists symptoms of problems relating to operational performance (no error codes displayed) and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-6: Operational Performance Problems

Condition	Recommended Action
1. The PULSE AMPLITUDE indicator seems to indicate a pulse, but the digital displays show zeroes.	<ol style="list-style-type: none">1. The sensor may be damaged; replace it.2. If the condition still persists, replace the UIF PCB.
2. SpO ₂ or pulse rate values change rapidly; PULSE AMPLITUDE indicator is erratic.	<ol style="list-style-type: none">1. The sensor may be damp or may have been reused too many times. Replace it.2. An electrosurgical unit (ESU) may be interfering with performance:<ul style="list-style-type: none">– Move the N-3000 and its cables and sensors as far from the ESU as possible.– Plug the N-3000 power supply and the ESU into different AC circuits.– Move the ESU ground pad as close to the surgical site as possible and as far away from the sensor as possible.3. Verify the SpO₂ performance with service mode menu items 31-39. Verify the pulse measurement function with the SRC-2.4. If the condition still persists, replace the UIF PCB.

Section 5: Troubleshooting**5.6.6 Stacked Operation**

Table 5-7 lists symptoms of problems encountered while in the stacked configuration with the N-3100 and recommended actions. Refer to the N-3100 service manual for more troubleshooting information.

Table 5-7: Stack Problems

Condition	Recommended Action
1. BATTERY IN USE/ BATTERY LOW indicators on the N-3000 and N-3100 light steadily while they are connected to AC via the external power supply. Both units are operational.	<ol style="list-style-type: none"> 1. Ensure that the power supply is plugged into an operational AC outlet. If it is, and the green indicator light is not lit, replace the power supply. 2. If the green SPS indicator is lit, ensure that the power supply is properly plugged into the N-3100. 3. Check the N-3000 fuse and replace if necessary.
2. BATTERY IN USE/ BATTERY LOW indicator on the N-3000 lights steadily but N-3100 does not while they are connected to AC. The units are operational.	<ol style="list-style-type: none"> 1. Ensure that a good docking connection exists between the N-3000 and N-3100. 2. Check the N-3000 fuse and replace it if necessary, as indicated in the <i>Disassembly Guide</i> section.
3. BATTERY IN USE/BATTERY LOW indicators on the N-3100 light steadily but N-3000 does not while they are connected to AC via the external power supply. Both units are operational.	Check the N-3100 fuses and replace if necessary, as indicated in the <i>Disassembly Guide</i> section of the N-3100 service manual.
4. The N-3000 and N-3100 do not operate when disconnected from the external power supply.	<ol style="list-style-type: none"> 1. The N-3000 battery may be discharged. To recharge the battery, keep the N-3000 connected to its external power supply. Confirm that the BATTERY CHARGING indicator lights. The monitors may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge. 2. If the battery fails to hold a charge, replace as indicated in the <i>Disassembly Guide</i> section.

Table 5-7: Stack Problems - Continued

Condition	Recommended Action
5. While operating on battery power, the N-3000 operates with BATTERY IN USE/BATTERY LOW indicator lighting steadily but N-3100 does not operate.	<ol style="list-style-type: none"> 1. Ensure that a good docking connection exists between the N-3000 and N-3100. 2. If the condition persists, recharge the battery. (The battery may have enough power left to operate the N-3000 but not the N-3100.)

5.6.7 Serial Port

Table 5-8 lists symptoms of problems relating to the serial port and recommended actions. If the action requires replacement of a PCB or module, refer to Section 6, *Disassembly Guide*.

Table 5-8: Serial Port Problems

Condition	Recommended Action
1. The measured voltages at the serial port (paragraph 3.3.5.3) are incorrect.	<ol style="list-style-type: none"> 1. Ensure the Communications PCB switch settings are as described in paragraph 6.5.1. 2. If the condition persists, replace the Communications PCB. 3. If the condition still persists, replace the UIF PCB.
2. The measured voltages at the serial port (paragraph 3.3.5.3) are correct but messages are not being transmitted or received.	<ol style="list-style-type: none"> 1. Perform the serial port loop back (menu item 61) and serial port transmit (menu item 62) tests in the service mode (paragraphs 4.3.29 and 4.3.30). If the tests are successful, recheck the message formats you are sending to the monitor, ensure that a good cable connection exists between PC and N-3000, and verify the baud rate using the service mode, menu item 60. (When connected to a PC in the RS-232 format, a baud rate above 19,200 should not be used.) 2. If the test fails, ensure the Communications PCB switch settings are as described in paragraph 6.5.1. 3. If the condition persists, replace the Communication PCB. 4. If the condition still persists, replace the UIF PCB.

SECTION 6: DISASSEMBLY GUIDE

- 6.1 Introduction
 - 6.2 Removing the Battery
 - 6.3 Battery Replacement
 - 6.4 Fuse Replacement
 - 6.5 Monitor Disassembly
 - 6.6 Removing the Alarm Speaker
 - 6.7 Removing the SpO₂ PCB and SpO₂ Controller PCB
 - 6.8 Removing the Communications PCB
 - 6.9 Removing the UIF and Display PCB
 - 6.10 Control Knob Assembly Replacement
 - 6.11 Lithium Battery Replacement
 - 6.12 Reassembly
-

6.1 INTRODUCTION

The N-3000 can be disassembled down to all major component parts, including:

- PCBs
- batteries
- cables
- function buttons
- chassis enclosures

The following tools are required:

- small, Phillips-head screwdriver
- medium, Phillips-head screwdriver
- needle-nose pliers or 1/4-inch socket
- 7/16-inch socket
- 7/16-inch torque wrench, 10 inch-pounds, required only when replacing knob

WARNING: Before attempting to open or disassemble the N-3000, disconnect the power cord from the N-3000.

Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.

Caution: Remove the battery before disassembling the unit.

Note: Some spare parts have a business reply card attached. When you receive these spare parts, please fill out and return the card.

6.2 REMOVING THE BATTERY

Caution: If it is necessary to apply AC power while the battery cover is removed, do not connect the SPS power supply to the monitor while the power supply is plugged into AC power. Instead, first connect the power supply to the monitor, then connect the power supply to AC power. Misalignment of the power supply cord connector with the lower docking connector may result in damage to the monitor. (This caution does not apply when the battery cover is attached to the N-3000.)

Section 6: Disassembly Guide

Perform the following steps to replace the battery.

1. Turn the N-3000 OFF by pressing the ON/STANDBY button.
2. Disconnect the monitor from the SPS power supply.
3. Set the N-3000 upside down facing you, as shown in Figure 6-1.

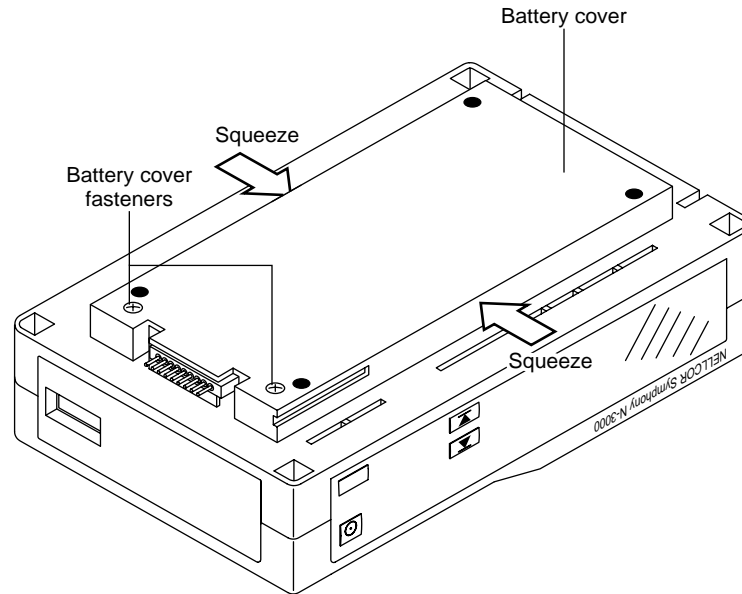


Figure 6-1: Battery Replacement

4. Loosen the two battery cover retaining fasteners securing the battery compartment cover.
5. Gently squeeze the battery cover sides in the middle as you swing the cover open (it is hinged on the right with three tabs that extend into slots on the chassis).
6. Lift the battery out of the battery bracket, as shown in Figure 6-2. It may be necessary to use the edge of a flat tip screwdriver to gently pry the battery loose.

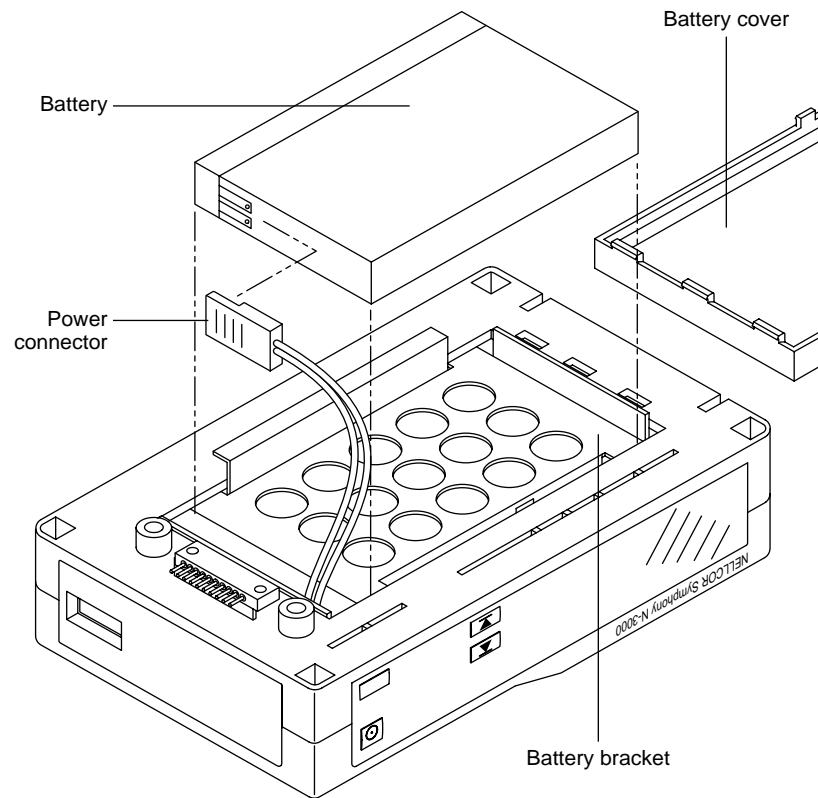


Figure 6-2: Removing the Battery

7. Disconnect the power connector from the battery.

6.3 BATTERY REPLACEMENT

1. Complete the procedure in paragraph 6.2.
2. The lead-acid battery is recyclable. Do not dispose of battery by placing it in the regular trash. Dispose of properly or return to Nellcor Puritan Bennett Technical Services for disposal.
3. Connect the power connector to the new battery. The connector can only be mated one way.
4. Position the battery into the battery bracket.
5. Replace the battery cover and tighten the retaining fasteners.
6. Turn the monitor on and verify proper operation.

Note: If the replacement battery is low on charge, the BATTERY CHARGING indicator may not light if the monitor is off and connected to AC power. If that is the case, turn the N-3000 on to begin charging.

Section 6: Disassembly Guide

6.4 FUSE REPLACEMENT

1. Complete the procedure in paragraph 6.2.
2. Replace the fuses as shown in Figure 6-3 with an equivalent replacement.

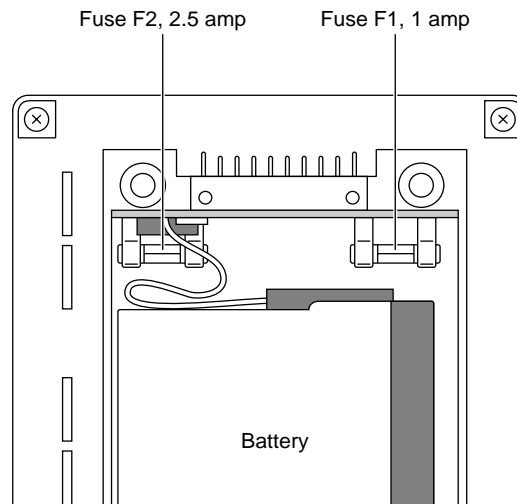


Figure 6-3: N-3000 Fuses

3. Reinstall the battery and battery cover.

Caution: The battery fuse (F2) on the Docking Connector PCB must be removed before disconnecting the docking connector cable from connector J17 as indicated in paragraph 6.5. Failure to remove the fuse may result in damage to the Lower Docking Connector PCB or UIF PCB.

6.5 MONITOR DISASSEMBLY

1. Complete the procedure in paragraph 6.2.
2. Remove the four corner screws that hold the monitor together (Figure 6-4).

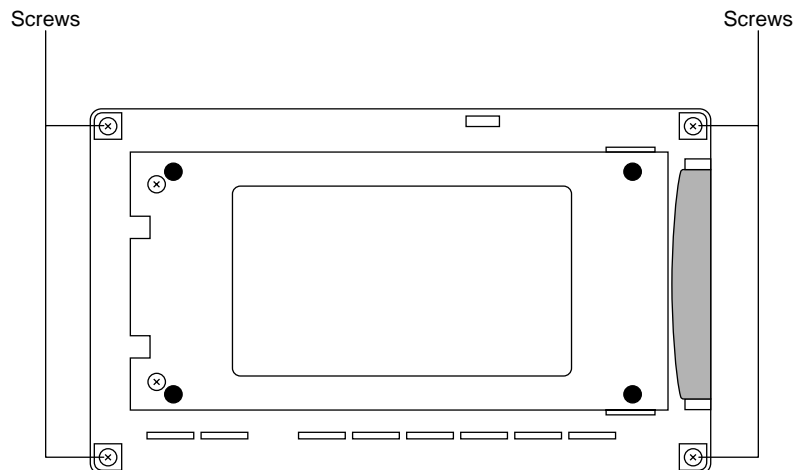


Figure 6-4: N-3000 Corner Screws

3. Pull the carrying handle down to the right.
4. Pull the unit apart, swinging the bottom half to your left, as illustrated in Figure 6-5.

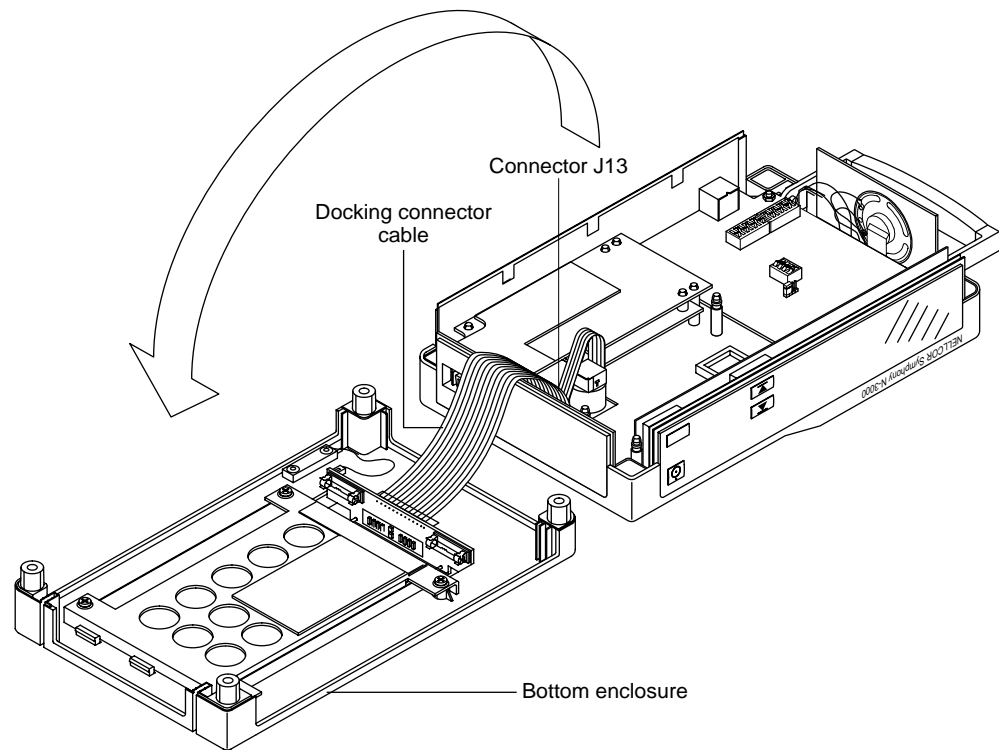


Figure 6-5: Opening the N-3000 Monitor

Caution: The battery fuse (F2) on the Docking Connector PCB must be removed as indicated in paragraph 6.4 before disconnecting the docking connector cable from connector J17. Failure to remove the fuse may result in damage to the Lower Docking Connector PCB or UIF PCB.

5. The docking connector cable is plugged into connector J13 on the UIF PCB. Disconnect the docking connector cable from connector J13 by gently pushing the top of the connector down, while pulling straight up on the cable.

6.5.1 Communications Board Switch Settings

1. To change the switch settings on your communications PCB, complete steps 1 through 4 in paragraph 6.5.
2. The switch settings on the Communication PCB are shipped for RS-232 communications and should be as follows (refer to Figure 6-5):
SW1 - Positions 1, 3, 5, and 7 = ON; Positions 2, 4, and 6 = OFF
SW2 - Positions 2, 4, and 6 = ON; Positions 1, 3, 5, and 7 = OFF
SW3 - Position 1 = ON; Position 2, 3, and 4 = OFF
Jumper J6 in "IGND" position.

Section 6: Disassembly Guide

If a continuous 3.3 volt signal at pin 6 of the serial port (Figure 3.3) is required (as when using the *Nellcor Puritan Bennett* SOC-3 adapter), change the SW3 settings as follows:

SW3 - Position 1 = OFF; Position 2, 3, and 4 = ON

If RS-422 settings are required, change SW1 and SW2 as follows:

SW1 - Positions 1, 3, 5, and 7 = OFF; Positions 2, 4, and 6 = ON

SW2 - Positions 2, 4, and 6 = OFF; Positions 1, 3, 5, and 7 = ON

SW3 - Position 1 = ON; Position 2, 3, and 4 = OFF

6.6 REMOVING THE ALARM SPEAKER

1. Complete the procedure in paragraph 6.5.
2. Remove the handle and spring assembly on the right side of the unit, as illustrated in Figure 6-6, lifting it up out of the molded chassis cradle.

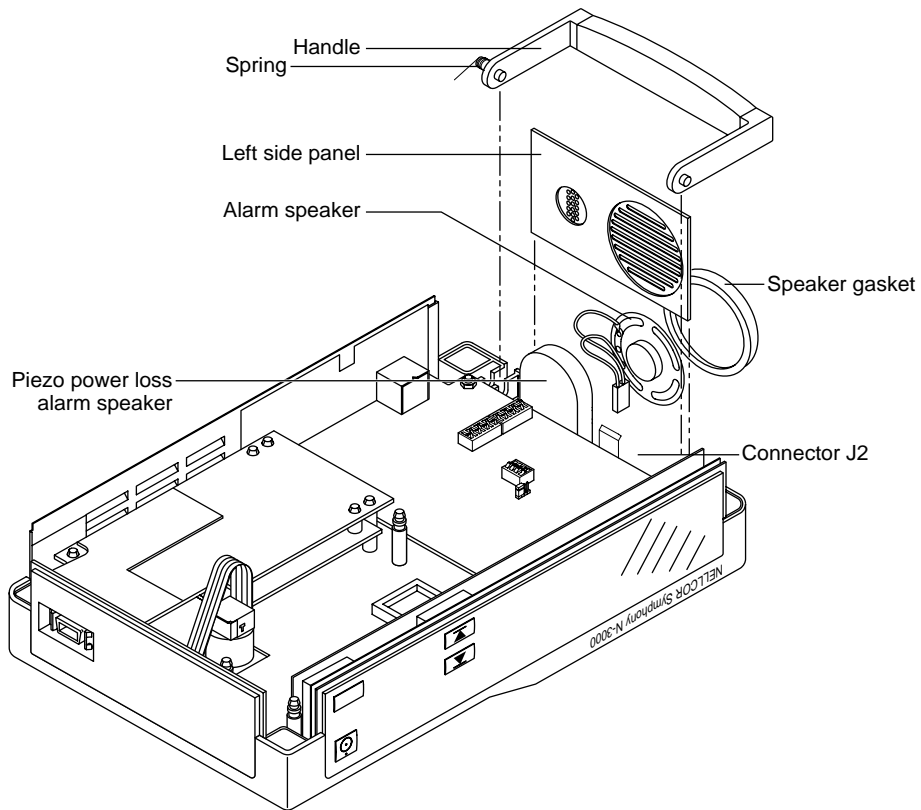


Figure 6-6: Handle, Left Side Panel, and Speaker Disassembly

3. Remove the left side panel (this is on your right, as illustrated above) by pulling straight up; be careful not to damage speakers.
4. Remove the alarm speaker cable by lifting up from connector J2 on the UIF PCB.

1. Complete the procedure in paragraph 6.5.
2. Remove the rear panel, rear-panel insulator, and NEW PATIENT/NEONATAL button by lifting up and rotating out of the chassis channel guides as illustrated in Figure 6-7.



- APL DEL00034540

Section 6: Disassembly Guide

6.8 REMOVING THE COMMUNICATIONS PCB

1. Complete the procedures in paragraph 6.6 and step 2 of paragraph 6.7.
2. Using a 1/4 inch socket or needle-nose pliers, remove the Communications PCB by removing the four 1/4-inch nuts that secure it to the UIF PCB (Figure 6-8). After removing the nuts, lift straight up.

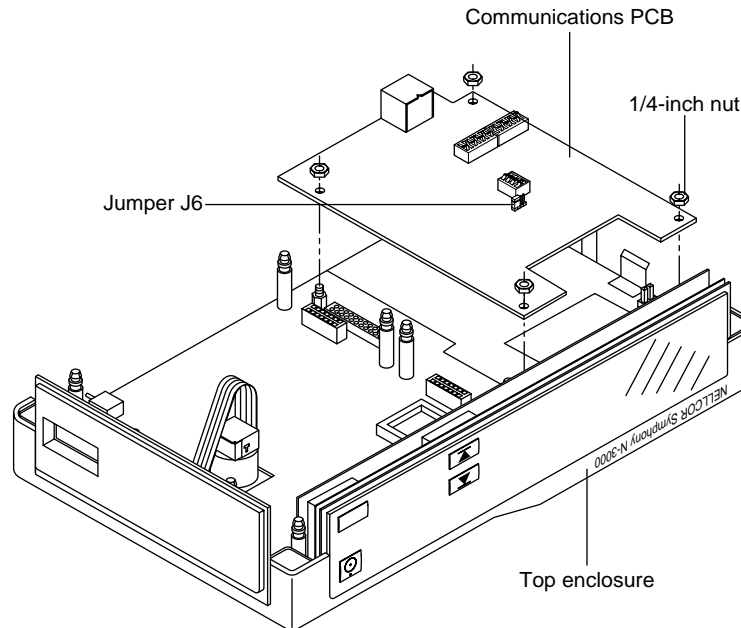


Figure 6-8: Communications PCB Removal

6.9 REMOVING THE UIF PCB AND DISPLAY PCB

1. Complete the procedures in paragraphs 6.7 and 6.8.
2. Remove the right-side panel by lifting it straight up.

3. Remove the front-panel bezel by gently lifting it up and rotating it away from the Display PCB as illustrated in Figure 6-9.

The display PCB is secured to the UIF PCB via the J5 connector. To remove the Display PCB, the UIF PCB must first be loosened to allow the Display PCB to be lifted out of the molded chassis housing slots.

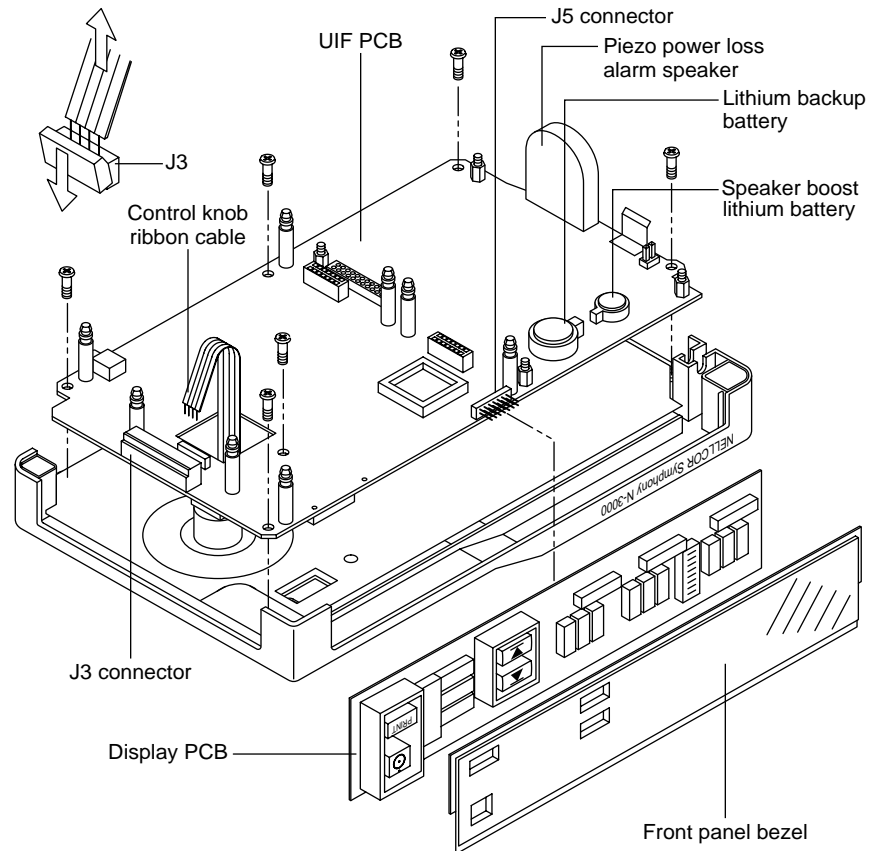


Figure 6-9: Display PCB and UIF Board Disassembly

4. Using a Phillips-head screwdriver, remove the six screws securing the UIF PCB to the chassis.
5. Remove the Display PCB by lifting up on the mother board, then pulling the Display PCB away from the UIF PCB and disconnecting from J5.
6. Disconnect the control knob ribbon cable from J3 on the UIF PCB. Push the top of the connector down, then pull the cable straight up and out of the connector.
7. Lift the UIF PCB out of the chassis housing.
8. When replacing the UIF PCB, the Instrument Identification label must be replaced. Attach the label to the enclosure on the bottom of the unit. Reset the configuration code if required. Confirm the number using the service mode menu item 17.

Section 6: Disassembly Guide

6.10 CONTROL KNOB ASSEMBLY REPLACEMENT

1. Complete the procedure in paragraph 6.9. The top cover appears as illustrated in Figure 6-10.

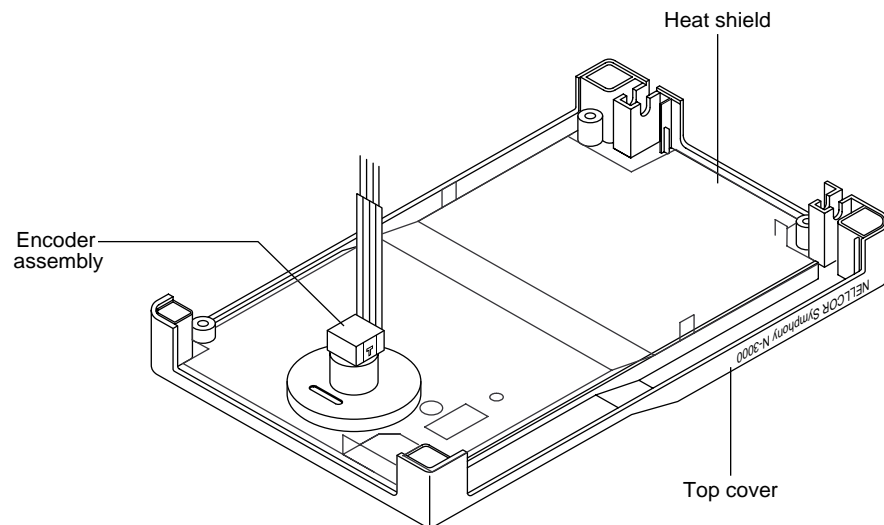


Figure 6-10: Knob Encoder Disassembly

2. Turn the cover right-side-up as illustrated in Figure 6-11 and use a small, flat blade to gently pry the knob off the shaft. When removing the knob in this manner, care must be taken not to nick and dent the surrounding top cover.

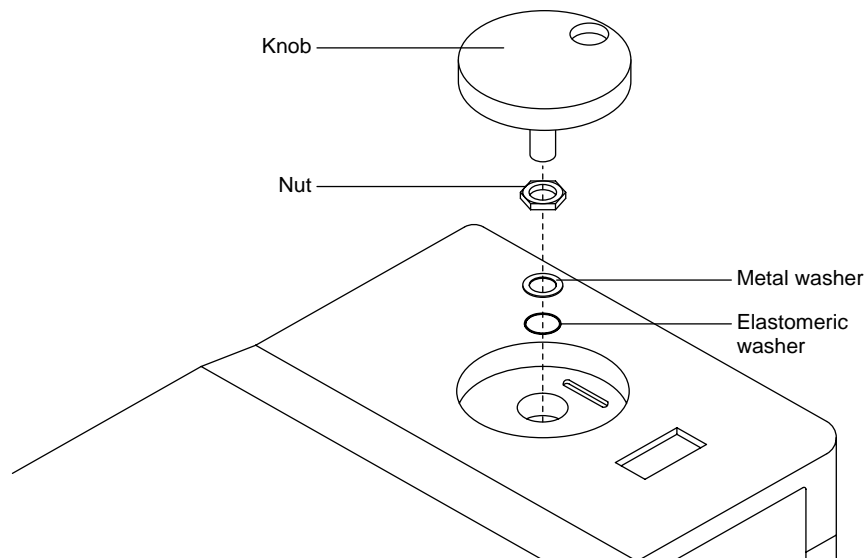


Figure 6-11: Knob Disassembly

3. Using a 7/16-inch socket, remove the nut securing the shaft and knob assembly to the chassis.

4. Replace the control knob assembly with the elastomeric washer closest to the plastic chassis. Torque nut to 10 inch-pounds. Replace the heat shield and white plastic insulator as illustrated in Figure 6-10.

6.11 LITHIUM BATTERY REPLACEMENT

1. Disconnect AC line voltage from the monitor.
2. With the monitor upside down and facing you, open up the chassis as shown in Figure 6-5.
3. Locate the lithium batteries on the UIF PCB (Figure 6-9). The backup lithium battery (the larger of the two lithium batteries) is used to supply backup power to the UIF processor if the lead-acid battery fails during DC use. It also supplies power to the piezo power loss alarm speaker during a microprocessor or power failure alarm. The other (smaller) battery provides additional voltage to power the piezo speaker.
4. Slide battery (or batteries) from underneath the spring clips. Do not dispose of lithium batteries by placing them in the regular trash. Dispose of properly or return to Nellcor Puritan Bennett Technical Services for disposal.
5. Replace batteries, observing correct polarity (positive terminal up). Ensure that they are secure.
6. Reassemble the chassis.

6.12 REASSEMBLY

Reassemble the monitor by performing the disassembly steps in reverse order.

1. Ensure that all plastic isolation shields are reinstalled correctly.
2. Ensure that the small wiper fingers that make contact with the side-panel metalized coating throughout the top chassis fit properly.
3. Ensure that all buttons are seated properly and operate smoothly.
4. All of the side panels have channel guides molded into the top and bottom chassis to assist in proper location and seating.
5. To install the handle, locate the small spring attached to one side. After all PCBs and side panels have been properly seated in the top chassis, install the handle into the cradle in a vertical position. Guide the spring into the molded channel located at the rear of the top chassis while leaning the handle to the inside of the unit. When properly seated, the handle will rotate out with a small amount of spring tension and naturally return to the vertical resting position.
6. Depending upon the level of repairs, you may have to reconfigure the monitor's Internal Configuration Code (ICC) in order to get the monitor to operate properly. Refer to the service mode section, menu item 21, of this manual.

SECTION 7: SPARE PARTS

7.1 Introduction

7.1 INTRODUCTION

Spare parts, along with part numbers, are shown below. Numbers in parentheses correspond to those in Figure 7-1.

Item No.	Description	Part No.
1	Cover, battery	031763
2	Battery, lead-acid, 12V-2Ah	640115
3	Bracket, battery	030487
4	Cover, bottom, monitor	031646
5	Handle, carrying	030783
6	Panel, left, speaker mount	030067
7	Gasket, speaker	032994
8	Speaker, with lead, connector and insulator	033115
9	PCB, communications, EPP	SP033446
11	Battery, lithium, small (3V, 12mm)	640112
12	Battery, lithium, large (3V, 23mm)	642002
15	Cover, top, without metal shield	024897
16	PCB, display	SP033057
20	Buttons, on/standby and print	030524
21	Buttons, set of 2, alarm limit	030711
22	Knob, control	024138
23	Encoder, with flexible type cable, optical	291169
26	PCB, UIF	SP033442-1
27	PCB, SpO ₂ controller	SP030097
28	Panel, rear	030065
29	PCB, SpO ₂	SP030063
31	Panel, front	033303
33	Panel, right	033101
34	Clip, grounding	031517
35	Button, audible alarm off	031853
36	Cable, 012 CKT, docking connector	030581
37	Gasket, rubber, SpO ₂	030974
38	Button, new patient/neonatal	023301
40	PCB, docking connector	SP030221
not pictured	SPS-N1 power supply	033877
not pictured	NPC-NA power cord	071505
not pictured	OXISENSOR II assortment pack	ASP3
not pictured	Cable, EIA-232, serial interface	030604
not pictured	Cable, input, sensor	SCP10
not pictured	Fuse, 1.0A, type-T, 250V, 5x20 mm	691208
not pictured	Fuse, 2.5A, type-T, 250V, 5x20 mm	691311

Section 7: Spare Parts

Figure 7-1 shows the N-3000 expanded view with numbered callouts relating to the spare parts list.

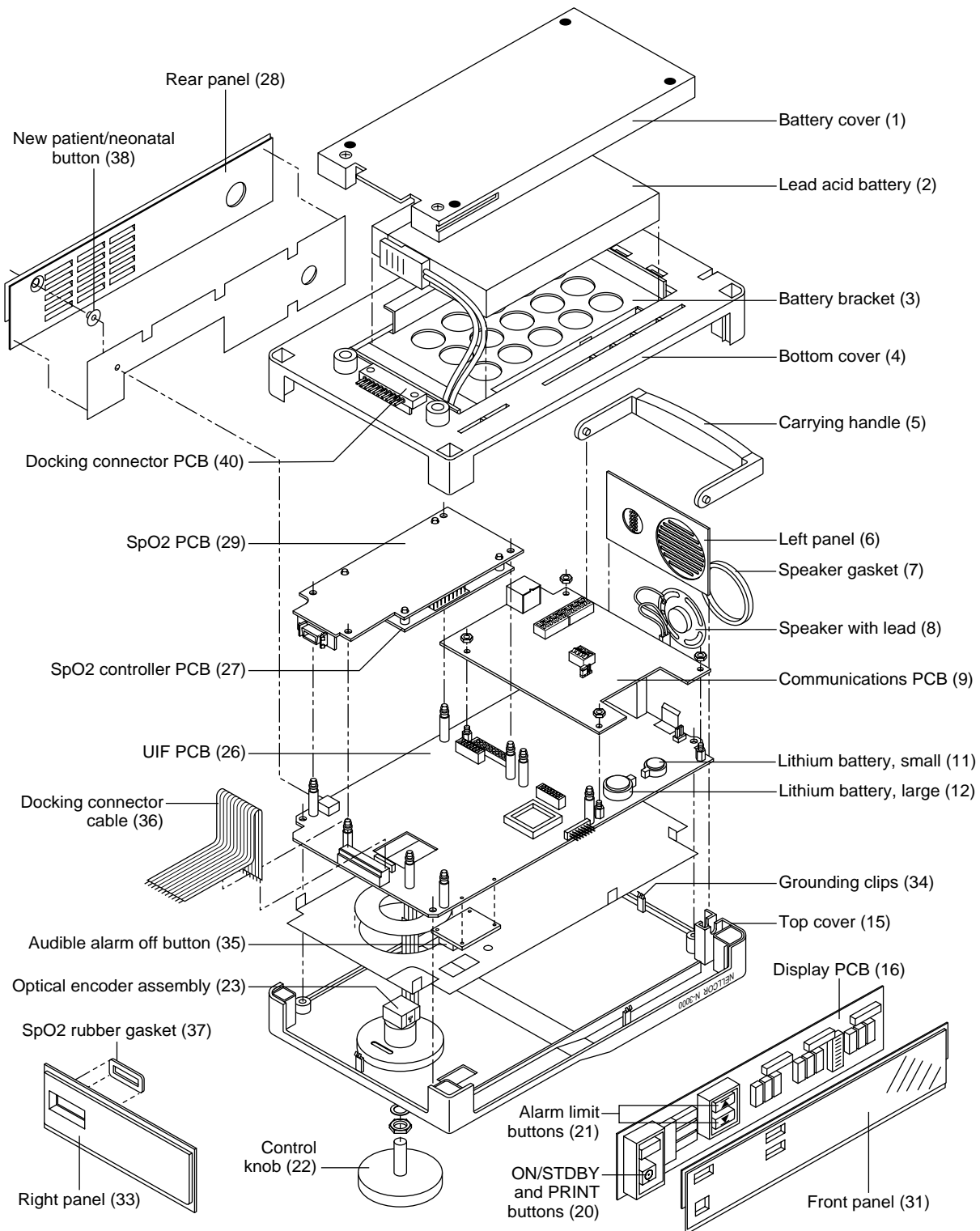


Figure 7-1: N-3000 Expanded View

SECTION 8: PACKING FOR SHIPMENT

- 8.1 General Instructions
 - 8.2 Repacking in Original Carton
 - 8.3 Repacking in a Different Carton
-

To ship the monitor for any reason, follow the instructions in this section.

8.1 GENERAL INSTRUCTIONS

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by the Nellcor Puritan Bennett warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Nellcor Puritan Bennett Technical Services to obtain a shipping carton.

Prior to shipping the monitor, contact your supplier or the local Nellcor Puritan Bennett office (Technical Services Department) for a returned goods authorization number. Mark the shipping carton and any shipping documents with the returned goods authorization number.

8.2 REPACKING IN ORIGINAL CARTON

If available, use the original carton and packing materials. Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.

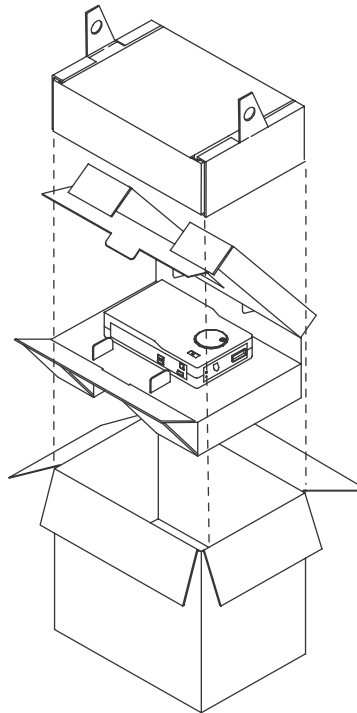


Figure 8-1: Repacking the N-3000

2. Place in shipping carton and seal carton with packaging tape.

Section 8: Packing for Shipment

3. Label carton with shipping address, return address and RGA number, if applicable.

8.3 REPACKING IN A DIFFERENT CARTON

If the original carton is not available:

1. Place the monitor in a plastic bag.
2. Locate a corrugated cardboard shipping carton with at least 200 pounds per square inch (psi) bursting strength.
3. Fill the bottom of the carton with at least 2 inches of packing material.
4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.
5. Seal the carton with packing tape.
6. Label the carton with the shipping address, return address, and RGA number, if applicable.

SECTION 9: SPECIFICATIONS

- 9.1 General
 - 9.2 Electrical
 - 9.3 Physical Characteristics
 - 9.4 Environmental
 - 9.5 Alarms
 - 9.6 Factory Default Settings
 - 9.7 Performance
-

9.1 GENERAL

Designed to meet safety requirements of:

UL 544, CSA-C22.2 No. 601.1-M90, IEC 601.1, IEC 601.1 (type CF),
ISO 9919, RFE per VFG 243, EMC per IEC 801 series.

9.2 ELECTRICAL

Protection Class

Class I: per I.E.C. 601-1, clause 2.2.4

Degree of Protection

Type CF: per I.E.C. 601-1, clause 2.2.26

Lead-acid Battery

Type	Rechargeable, sealed, internal
Operating time	4 hours minimum on full charge when operating standalone; 2 hours minimum when attached to an N-3100 blood pressure monitor
Recharge period	14 hours for full charge; 6 hours for 1 hour of operating time

Lithium Batteries

3V, 12mm, coin
3V, 23mm, coin

Input Voltage 15VDC

Fuses F1: 1.0A, 250V, Slo-Blow
F2: 2.5A, 250V, Slo-Blow

External Power Supply

Model SPS-N or SPS-N1 AC input: 100–120 VAC, 500 mA (maximum),
50/60 Hz

Section 9: Specifications

9.3 PHYSICAL CHARACTERISTICS

Dimensions	6.8 cm x 23.9 cm x 14.7 cm (2.65 in. x 9.41 in. x 5.79 in.)
Weight	1.8 kg (3.96 lb.)

9.4 ENVIRONMENTAL

Operating Temperature	5 ° to 40 °C (+41 °F to +104 °F)
Storage Temperature	-40 ° to +70 °C (-40 °F to +158 °F)
Operating Altitude	-396m to +3,139m (-1,300 ft. to +10,300 ft.)
Relative Humidity	15%RH to 95%RH, noncondensing

9.5 ALARMS

Alarm Limit Range	
% Saturation	20–100%
Pulse Rate	30–250 bpm

9.6 FACTORY DEFAULT SETTINGS

Factory Default Alarm Settings

	Adult	Neonate
SpO ₂ Upper Alarm Limit:	100%	95%
SpO ₂ Lower Alarm Limit:	85%	80%
Pulse Rate Upper Alarm Limit:	170 bpm	190 bpm
Pulse Rate Lower Alarm Limit:	40 bpm	90 bpm

General Factory Default Settings

	Default Setting
Operating Mode:	Adult-Pediatric
Pulse Beep Volume:	57.5 dB(A) at 1 meter (step 6)
Audible Alarm Volume:	61 dB(A) at 1 meter (step 8)
Audible Alarm Silence Period:	60 seconds
Alarm Silence Reminder:	ON
Latching Alarms:	OFF
Trend Format:	10-second averaged (Format 1)
Serial Port Baud Rate	19,200 bits per second

9.7 PERFORMANCE

Range

Saturation: 0–100%

Pulse Rate: 20–250 bpm

Accuracy

SpO₂

Adults:	70–100% ± 2 digits 0–69% unspecified
Neonatal:	70–95% ± 2 digits 0–69% unspecified

Accuracies are expressed as plus or minus “X” digits (saturation percentage points) between saturations of 70–100%. This variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population. All accuracy specifications are based on testing the subject monitor on healthy adult volunteers in induced hypoxia studies across the specified range. Adult accuracy is determined with *OXISENSOR* II D-25 sensors. Neonatal accuracy is determined with *OXISENSOR* II N-25 sensors. In addition, the neonatal accuracy specification is neonatal blood on oximetry measurements.

Pulse Rate (SpO₂ optically-derived) 20–250 bpm ± 3 bpm

Accuracy is expressed as plus or minus “X” bpm across the display range. This variation equals plus or minus 1SD, which encompasses 68% of the population.

APPENDIX

- A1 Integrity Tests
 - A2 Error Types
 - A3 User Correctable Error Codes
 - A4 Failure Error Codes
 - A5 Internally Corrected Error Codes
-

A1 INTEGRITY TESTS

The N-3000 routinely performs internal system integrity tests to verify and monitor proper operation. As a result, error codes are recorded in the monitor internal Error Log and codes may be displayed on the monitor front-panel display. These error codes help establish a starting point for troubleshooting the N-3000.

Failure error codes are produced by the N-3000 when one of the following automatic integrity tests detects an error:

- **POST (Power-On Self-Test) and Watchdog:** The POST verifies processor memory, display, speaker, communications, time sense device, control logic, and SpO₂ hardware. The watchdog circuit monitors the operational status of the processor.
- **Background Test:** Background tests are periodically run during normal operation and check the memory integrity, processor operation, and secondary lithium battery voltage. Internal communication variables and parameters are checked for the appropriate values and timeliness.
- **Failure Error Detection:** A failure error may occur at any time. The failure error detection process attempts to make an entry into the error log, displays an error code, sounds an alarm, and places the instrument into a state (including ceasing monitoring) that minimizes the chance of additional risk to the patient or caregiver.

Appendix**A2 ERROR TYPES**

There are six classes of errors in the N-3000, as indicated in Table A-1.

Table A-1: Error Types

Error Type	Description
1. Generic POST/processor failure.	In this case, nothing may happen, or a shrill continuous alarm may sound and the display may go blank. This represents a severe hardware failure. For example, the UIF processor could not activate the display or speaker facilities.
2. Initialization failure.	An EEExxx code representing the failure is displayed and a low-priority alarm sound is produced, but no entry is made in the Error Log. POST has proceeded to the point that the UIF processor has control of the display and speaker facilities. The error cannot be logged because the Error Log portion of the EEPROM has failed, or internal communications to the Error Log cannot be established.
3. Failure error at the end of initialization or during steady state operation.	An EEExxx code representing the failure is displayed, a low-priority alarm sound is produced, and a "failure" class error entry is made in the Error Log.
4. Internally corrected error.	These errors do not appear on the display, neither do they cause an alarm. However, they are entered in the Error Log. These errors represent events that have occurred in the instrument that are undesirable, but for which the instrument has effective means of recovery. This includes such things as watchdog resets, data stream restarts due to data under-run or stoppage, and resource exhaustion, for example, not enough memory buffers or not enough CPU cycles.
5. User-correctable error.	An EEE0xx code representing the failure is displayed and a low-priority alarm sound is produced, but no entry is made in the Error Log. These errors represent hardware failure conditions that can be corrected by the user, such as replacing a faulty sensor or cable. They are not logged because they are caused by equipment external to the N-3000. They are readily identified by the 0 leading digit in the error number displayed along with EEE (failure errors have a leading digit other than 0).
6. Unexpected loss of power.	This results in a shrill, pulsing alarm sound. Nothing is logged in the Error Log and the display is blank because the primary power in the instrument has failed. This alarm is powered by the secondary back-up lithium batteries located on the UIF board.

In all cases, an attempt to store an error in the Error Log may fail due to failure or corruption of the Error Log in EEPROM. This condition alone does not constitute a failure error and operation of the instrument proceeds as if the error has been successfully logged.

A3 USER-CORRECTABLE ERROR CODES

The error codes listed in Table A-2 are user-correctable.

Table A-2: N-3000 User-Correctable Error Codes

Error Code	Explanation
055	Current user input values (limits, volumes, times) have been lost during an internal reset and the unit has returned to power-on defaults.
058	Alarm and beep volume, audible alarm silence duration and operating mode have returned to power-on defaults due to an internal instrument reset.
081	Cannot calibrate sensor.

A4 FAILURE ERROR CODES

Table A-3 lists the possible failure error codes in numerical order. Refer to Table 5-3 for a list of corrective measures.

Table A-3: N-3000 Failure Error Codes

Error Code	Explanation
114	UIF excessive watchdog resets.
108	Battery/Power management failure.
109	Stackbus gating failure.
110	Lithium battery voltage too low.
111	UIF unknown POST failure (typically, processor derail or memory corruption during POST).
151	UIF startup problem, missing resource, or unexpected state during module initialization.
159	Unable to complete operation. Institutional parameters are in unknown state.
175	UIF unable to send data over internal stack bus.
176	UIF unable to receive data over internal stack bus.
177	UIF unable to communicate with stacked instruments
178	EEPROM CRC failure (configuration EEPROM).
179	Missing or non-responding module.
183	Illegal operating mode change.

Table A-3: N-3000 Failure Error Codes - Continued

Error Code	Explanation
189	UIF RTC failure.
192	Duplicate node detected.
195	Incompatible software.
196	Illegal mode combination in stack.
203	SpO ₂ controller failure.
204	SpO ₂ digital section failure.
205	SpO ₂ controller clock failure (check SpO ₂ digital board clock select jumper and digital board to analog board connection).
206	SpO ₂ processor clock failure.
211	SpO ₂ unknown POST failure.
275	SpO ₂ unable to send a command to UIF module.
276	SpO ₂ commands physically but not logically accepted by UIF module or SpO ₂ receiver broken.
283	Illegal operating mode change.

A5 INTERNALLY CORRECTED ERROR CODES

Internally corrected error codes are not normally displayed. These errors are logged on the internal Error Log, then the N-3000 watchdog circuitry resets the monitor. They can be accessed only by using the Service Mode (menu items 7 through 16) as indicated in Paragraph 4.3, Service Mode.

Table A-4 lists the internally corrected error codes in numerical order. It is not normally necessary for service personnel to access the Error Log. However, if you find it necessary to contact Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative, they may request information from the Error Log.

Table A-4: N-3000 Internally Corrected Error Codes

Error Code	Explanation
101	General failure of UIF Generic POST.
125	UIF cannot allocate a resource (ran out of a dynamic resource, memory corruption during initialization, or a logic error resulting from a low-probability combination of events that did not appear in unit or validation testing).
126	UIF stack overflow.
150	UIF general watchdog reset.
152	UIF memory corruption.
153	UIF unexpected interrupt.

Table A-4: N-3000 Internally Corrected Error Codes - Continued

Error Code	Explanation
154	UIF RTXC executive function failed.
156	UIF stack communication bus common code failed.
157	UIF state machine illegal transition or unknown state.
180	External Port Service internal error (RS232 handler).
184	UIF Data stream or Reply timeout.
225	SpO ₂ can't allocate a resource.
226	SpO ₂ stack overflow.
250	SpO ₂ general watchdog reset.
252	SpO ₂ memory corruption.
253	SpO ₂ unexpected interrupt.
254	SpO ₂ RTXC executive function failed.
256	SpO ₂ communication bus common code failed.
257	SpO ₂ state machine illegal transition or unknown state.
278	SpO ₂ cannot get power-on defaults from EEPROM or they are invalid (bad values or low-limit above high-limit).
283	Operating mode changed during internal reset.
285	SpO ₂ Controller PCB failure.
286	SpO ₂ PCB failure.
287	SpO ₂ detected failure of other system component (UIF PCB, UIF software, or communication problem).
288	SpO ₂ module failure (cannot determine whether SpO ₂ Controller PCB or SpO ₂ PCB).

TECHNICAL SUPPLEMENT

S1	Introduction
S2	Oximetry Overview
S3	Stackbus Interconnect
S4	Circuit Analysis
S5	Schematic Diagrams

S1 INTRODUCTION

This Technical Supplement provides the reader with a discussion of oximetry principles and a more in-depth discussion of N-3000 circuits. A functional overview and detailed circuit analysis are supported by block and schematic diagrams. The schematic diagrams are located at the end of this supplement.

S2 OXIMETRY OVERVIEW

Pulse oximetry is based on two principles:

- Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
- The volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography).

A pulse oximeter determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO₂ measurements on the difference between maximum and minimum absorption (that is, measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

S2.1 Automatic Calibration

Because light absorption by hemoglobin is wavelength-dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO₂. During manufacturing, a resistor in the sensor encodes the mean wavelength of the red LED. During monitoring, the instrument's software reads this resistor and selects coefficients that are appropriate for the wavelength of that sensor's red LED; these coefficients are then used to determine SpO₂. This resistor is read when the monitor is turned on, periodically thereafter, and each time a new sensor is connected.

Additionally, to compensate for differences in tissue thickness, the intensity of the sensor's LEDs is adjusted automatically.

Technical Supplement**S2.2 Functional Versus Fractional Saturation**

This monitor measures functional saturation — oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation — oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\% \text{ carboxyhemoglobin} + \% \text{ methemoglobin})} \times 100$$

S2.3 Measured Versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO₂), the calculated value may differ from the SpO₂ measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO₂ and saturation (Figure S2-1): pH, temperature, the partial pressure of carbon dioxide (PCO₂), 2,3-DPG, and fetal hemoglobin.

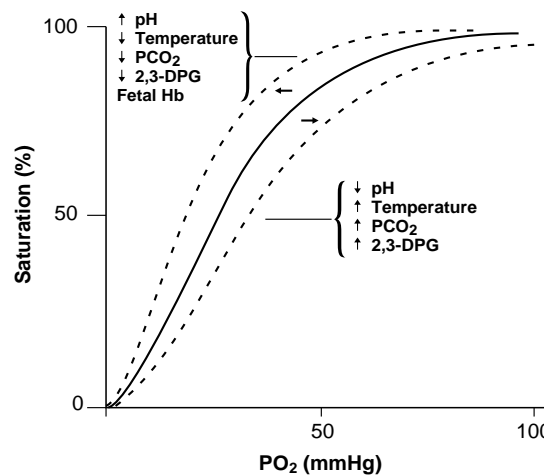


Figure S2-1: Oxyhemoglobin Dissociation Curve

S3 STACKBUS INTERCONNECT

Stackbus is the term for the communication interconnect between the N-3000 modules and also between the N-3000 and N-3100 instruments.

The internal stackbus is used for communications between the UIF PCB and the SpO₂ module. Information is transmitted over a single PCB trace using the Arcnet (discussed in paragraph S4, Circuit Analysis) local area network standard as the message protocol.

The external stackbus is used for communications between the N-3000 and the N-3100. Information is exchanged over two pins on the N-3000 docking connector and two sockets on the N-3100 upper docking connector. As with the internal stackbus, the Arcnet local area network standard is used as the protocol. RS-485 drivers and receivers are used for signaling. A proximity sensor in the bottom of the N-3000 or N-3100 detects when the monitor is docked, enabling the stackbus signals.

Access to the stackbus is accomplished through token passing. A token designates which station (module or instrument) has control of the stackbus. The token is passed in a circular manner from station to station. The station holding the token has the exclusive right to transmit onto the stackbus, but the right to transmit may be temporarily donated to another station to acknowledge a transmission by the token holder. The token holder must relinquish control of the stackbus by passing the token to the next station on the loop within a specified period of time. During normal operation, the right to access the stackbus passes from station to station in a continuous, consistent manner.

All instruments participate in the loop when stacked and powered-on. Maintenance of the token passing, loop initialization, lost token recovery, and the addition of new stations is implemented in the N-3000's UIF and SpO₂ modules and in the N-3100 by the specialized devices and system software.

S4 CIRCUIT ANALYSIS

This section provides a descriptive overview of the N-3000 modular design, as well as a circuit description.

S4.1 Functional Overview

The monitor functional block diagram is shown in Figure S4-1. Central to the PCB modules is the UIF module. This module receives power from an external AC source or battery via the docking connector. It supplies power to the other modules connected to it, while also communicating with them via the stackbus. It controls user interface and network gateway functions.

Connected to the UIF module is the SpO₂ module, which consists of two PCBs: the SpO₂ Controller and the SpO₂ PCB. The SpO₂ Controller board contains the micro controller, memory system, internal stackbus interface, and other control logic. The SpO₂ PCB contains all the analog signal conditioning and control hardware necessary to measure SpO₂. The two boards are electrically connected by a single interface connector.

The Communications module allows messages to be sent to a host computer using asynchronous serial communications. All communications signals on the Communications module originate from the UIF module.

The Display module contains annunciators and push buttons, allowing the user to access information and to select various available parameters. The Display PCB contains SpO₂ and heart rate LEDs and their associated driver circuits. Front-panel switches also allow the user to turn the unit on and off, to set alarm limits and to print data. The Display PCB is connected to the UIF module via a 14-pin connector.

Technical Supplement

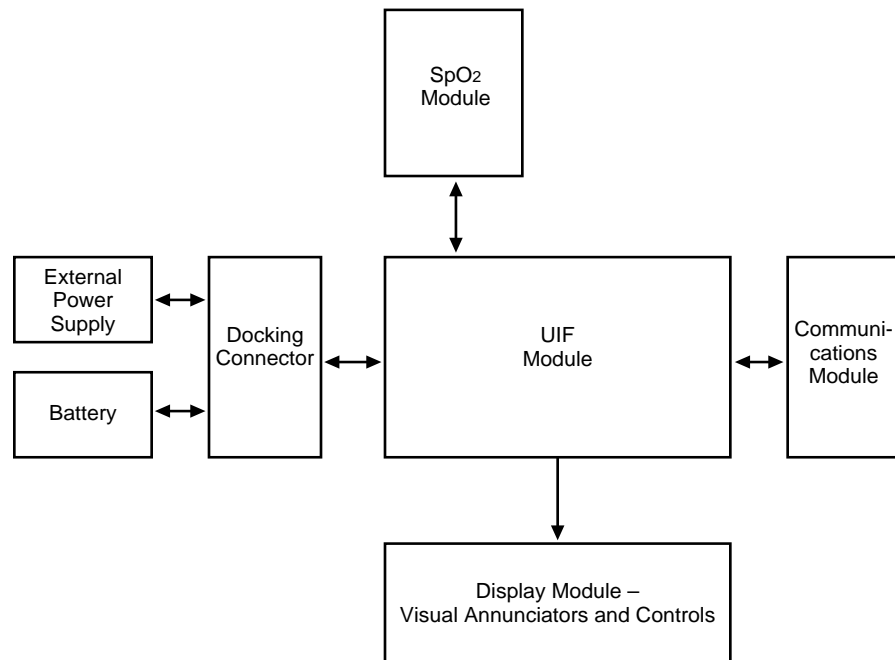


Figure S4-1: N-3000 Functional Block Diagram

S4.2 Circuit Description

The following paragraphs discuss the operation of each of the printed circuit boards within the N-3000 oximeter. (Refer to the appropriate schematic diagram at the end of this supplement, as necessary.)

S4.2.1 SpO₂ Module

a. Isolated Power Supply

Transformer T1 and associated components comprise the isolated power supply circuitry of the SpO₂ module (see sheet 1 of the schematic diagram). This power supply is a pulse-width modulated, current-mode, switching supply. In this circuitry, controller U4 is synchronized to a programmable clock frequency, ANALOG CLK (U4, pin 4). Timing for the isolated circuitry is derived from the switching frequency of the power supply, hence ANALOG CLK is used to control front-end aliasing. If no ANALOG CLK signal is available, R13 and C8 provide a default timing circuit for the U4 controller.

Two parallel FETs, Q7, drive the T1 transformer in flyback mode, channeling the current through sense resistors R23 and R133. Any inductive spike created by the leakage inductance of the T1 transformer is filtered out of the circuit by R105 and C9.

Feedback for the U4 controller is optocoupled through one-half of U34. This controls the circuit pulse width, which also maintains the isolated VCCI at 5 volts. Components R68, R69, R70, C45, and CR8 detect the value of VCCI and increase the output of the optocoupler when it (VCCI) is over 5 volts.

The transformer flyback pulse is rectified by CR7 and filtered by C12, C57, and R5 to create VCCI. The other two transformer windings have three times as many turns as the VCCI winding. These windings are rectified by CR5 and CR6 to achieve ± 15 volts during the flyback cycle. These supplies are then regulated by U2 and U15 to ± 12 volts.

Normal transformer signals are filtered out of the circuitry by C55, R110, CR2, Q3, R38, C14, Q6, R53, and R49. However, the Q7 turn on transition is a direct result of the ANALOG CLK signal. This creates the isolated clock signal (ISO CLK) and guarantees a consistent output pulse time independent of the pulse width modulation and inductive transient changes.

b. Timing

The ISO CLK is divided by U29 and decoded by U1 and U30 to create the timing signals used throughout the isolated section of the circuit. The timing diagram (Figure S4-2) shows the result of this decoding. One complete cycle of the front end takes 16 ISO CLK cycles.

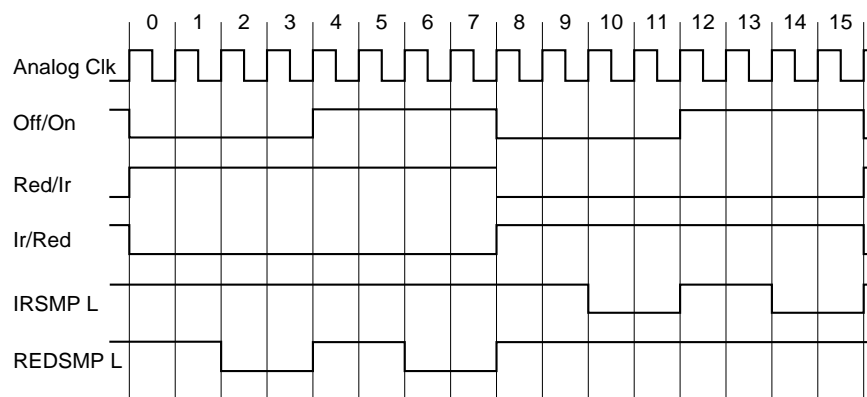


Figure S4-2: Timing Diagram

c. Microprocessor Control of Isolated Circuitry

Controller U10 (sheet 2 of schematic) is an Octal 8-bit DAC. The reference voltage for U10 is 5 volts, created by U39. Two U10 outputs, VOUTA and VOUTB, are used to program the LED outputs for the IR and RED channels. The other six signal lines are used as logic lines. Five control amplifier gain: PD0 and PD1 select the predemodulation gain, while DM0, DM1, and DM2 control the demodulated gain. The remaining signal line, CAL (U10, pin 18), selects the calibration setting.

d. LED Drive

The LED drive circuitry is shown in the lower left corner of the schematic diagram, sheet 2. Signal outputs from U10 — RED LED and IR LED — are used to control LED brightness. These signals are multiplexed by U31 and buffered by one-half of U32. A voltage divider circuit consisting of R101 and R102 divide the multiplexed signal down to the proper voltage to use as a reference for the other half of U32.

Additionally, R92 provides a path for stray current during the off period to ensure that the LEDs are truly off. Components R97, R98, and Q12 provide secondary protection against over-current drive by disabling the control op amp if the voltage goes above 0.9 volts.

Components R30 and C24 filter any high-frequency noise on VCCI that is beyond the bandwidth of U32. Finally, Q13, R104, and R105 turn the LEDs off between pulses.

e. Differential Input Amplifier

Input op amp U23 converts the differential current to a voltage. One side of the output is coupled through capacitor C48 while the other output is used as a reference that is switched by U24 onto R78 only during one channel on/off cycle. This AC couples only one channel.

Low frequency noise on the other channel is eliminated also since the LED-off output for both channels is the same. This switched AC coupling removes the DC without resulting in channel crosstalk. The resulting AC-coupled signal and reference are switched through U25 to the input of differential amplifier U21 when the patient module is plugged in.

If the cable is plugged in, U25 selects the output of the preamp and ground as the input to U21. AC coupling is performed to keep crosstalk from the preamped AC signal. Differential amplifier U21 has a programmable gain of 1, 4, 16, or 64, depending upon the state of PD0 and PD1.

f. Synchronous Demodulator and Gain

If calibration is not selected, the output of U21 is directed through U26 to filter U27 to eliminate high-frequency noise. Amplifier U28 is either an inverting or noninverting amplifier, depending on the state of switch U26.

U3 samples the output to demodulate the two channels. This sample-and-hold is then amplified by U5 or U6. The gain is 1 or 16, depending upon the state of DM2 from the U10 controller. The other half of U5 (or U6) drives the linear opto-isolator to create a current output proportional to the input voltage. This current has an effective gain of 1, 2, 4, or 8, controlled by DM0 and DM1. U13 converts the current output of the linear opto-isolator (U6) to a voltage and then to a digital value.

g. Auto Calibration

Switch U26 selects either the differential amplifier (U21) output or the internal calibration signals as an input to the U27-based filter. If the calibration input is selected, U24 can select either a zero or test input.

The zero input connects the filter input to ground so the system can calibrate the no-signal output of the two channels. The test input connects the LED current waveform to the filter so the demodulator has an output proportional to the programmed LED current.

h. Nonisolated Power Supply

The power supply creates ± 5 volt from the system battery supply. The input voltage is 8–16 volts, which is filtered and regulated by U19 to create the +5 volts. U20 converts this input to a regulated -7 volt output that is regulated to -5 volts by U18.

S4.2.2 UIF Module

The user interface (UIF), network gateway, and battery charge functions are controlled by the UIF module. This module provides power to the other modules within the N-3000, controls communication between each module via the stackbus, and provides charge control for the lead-acid battery.

a. Power and Battery Charging

Power from the lead-acid battery or the lower docking connector is delivered via the lower docking board ribbon cable connected to J13. Pin 1 of J13 is BATTPLUS1 and Pin 6 of J13 is CHARGEBUS. Pin 2 of J13 is earth ground and Pin 5 is system ground. These pins are defined in table S4-1. Both CHARGEBUS and BATTPLUS1 are connected using diode isolation and then connected through the drain of power transistor Q10 and Pin 7 of J13 (BATTBUS) to other stacked instruments.

Power switching and battery charging are controlled by U20, a BQ2001 power monitor IC.

The BQ2001 power monitor IC has three sources of power input: CHARGEBUS from the SPS-N or SPS-I power supply, the N-3000 lead-acid battery, or lithium battery BT1. The ON/STANDBY button is connected to BQ2001, which controls the gate of power transistor Q10. Processor U3 is also connected to BQ2001, receiving interrupts and reading data from the BQ2001 status registers when the N-3000 is on.

When the N-3000 is OFF (standby mode) and the ON/STANDBY button is pressed, the BQ2001 enables transistor Q10 and analog power from either the CHARGEBUS or the lead-acid battery is supplied to the 5V regulator (U17 and U18) and the SpO₂ module. It also signals the processor with an interrupt that there is new data in its status registers for the processor to read. As soon as the processor powers-up and clears reset, it will process the interrupt from the BQ2001 and begin to execute its program.

Table S4-1: J13 Inter Stack Connector

Pin No.	Pin Description	Input/Output/Power
1	Positive battery terminal (fused)	Power
2	Chassis (case) ground	Power
3	Stackbus differential +	I/O
4	Stackbus differential -	I/O
5	Digital ground	Power
6	Charge bus (15V)	Power
7	Battery bus voltage	Power
8	Proximity signal	Input
9	Not used	n/a
10	Not used	n/a
11	Not used	n/a
12	Battery charge	Power

When the N3000 is on and the ON/STANDBY button is pressed, the BQ2001 signals the processor via interrupt that there is data for the processor to read. When the processor reads the status, it determines that the unit should be turned off and signals the BQ2001 to disable Q10.

Other sources of interrupt from the BQ2001 are a low voltage from lithium battery BT1, the application or removal of CHARGEbus power, and the lead-acid battery voltage falling below a threshold preset by the processor.

When the SPS power supply is connected to the lower docking connector and connected to AC, CHARGEbus has a voltage of $15V \pm 0.75V$. This powers the battery charge overcurrent and overtemperature circuitry. The BQ2001 controls battery charging. When the processor senses that the battery needs charging, it tells the BQ2001 to turn on transistor Q5 for a programmed length of time. The BQ2001 will continue charging the battery as long as there is CHARGEbus available and its internal charge time register has not expired regardless of the mode of the N3000, unless it is told to stop by the processor or it senses that the over-temperature circuit has tripped.

The battery charging circuitry is a constant voltage charger. When the battery is discharged, its output voltage is low (about 10V) and the maximum charge rate (approximately 350mA) is applied to it. As the battery charges, its output voltage rises, reducing the amount of current delivered to it by CHARGEbus. When the battery is fully charged (about 14V), the charge rate decreases to 0 mA.

The over-temperature cutoff circuitry is physically located close to the power transistor used to charge the battery by the BQ2001. When the area around the transistor approaches 70° C, the circuit will signal the BQ2001 to stop charging. When the transistor cools, charging is resumed.

To protect the battery, a thermal cutoff switch is located on the docking connector close to the lead-acid battery compartment. When the temperature in the battery compartment approaches 50° C, the switch opens to prevent damage to the lead-acid battery.

b. Processor

The processor for the UIF PCB is U3, a Motorola MC68331 IC. This processor uses a 32-bit CPU and contains several submodules, including pulse-width modulators, internal RAM, and a Queued Serial Module (QSM). The processor also contains a non-multiplexed, data/address bus and input/output timer pins.

The processor generates chip selects, address lines, data direction, and data strobes for communicating with its peripherals over its bidirectional, 16-bit data bus D15 through D0. The chip select outputs are /CSBOOT and /CS0 through /CS8. The address lines are A0 through A18. The data direction is generated by U3 on R/W. The data strobe for indicating valid data is generated on /DS. Using these control lines, the processor is capable of reading from or writing to any of the peripherals attached to its data bus. Data transfers are either 16-bit (D15 through D0) or 8-bit (D15 through D8).

A 32.679 kHz source clock signal for the processor is produced by stackbus adapter U14 from crystal Y3. System clock frequency is chosen by software.

c. Processor Peripheral ICs

Processor U3 uses serial and parallel peripheral ICs.

The serial peripheral ICs communicate with the processor through the 68331 Queued Serial Module (QSM). These ICs are the Real Time Clock (RTC), the Electrically Erasable Read Only Memory (EEROM) and the display controllers located on the Display PCB.

The parallel peripheral ICs communicate with the processor through a non-multiplexed data bus. The ICs are processor code PROM U10, processor RAMs U13 and U23, Arcnet communications IC U6, digital-to-analog converter U5, analog-to-digital converter U27, stackbus adapter U14, BQ2001 power management chip U20, and UART (Universal Asynchronous Receiver Transmitter) U24.

Real Time Clock — The clock is a continuously running IC used by the processor to maintain time and date information. When the N-3000 is not on, the RTC is maintained by lithium backup battery BT1.

Electrically Erasable Read Only Memory — The EEROM is used by the processor to store institutional defaults and system error code data.

Display Controllers — These controllers are used by the processor to display data on the display board.

Processor Code PROM (U10) — The PROM contains the program that the processor uses to perform the user interface and gateway functions for the N-3000. Processor U3 address lines A1 through A17 are connected to PROM addresses A0 through A16, allowing even word address access to the PROM. To allow the use of either a 256K x 16 or 128K x 16 PROM at U10, Pin 43 of U10 is connected to J10 Pin 2. On a 256K x 16 PROM, Pin 43 will be PROM address A17. On a 128K x 16 PROM, Pin 43 will be an active high output enable. Address line A18 from U3 is connected to J10 pin 1 and VDD is connected to J10 pin 3. Attaching a jumper between J10 pins 1 and 2 will connect U3 address line A18 to PROM address A17 to address all 256K words in a 256K x 16 PROM. Connecting a jumper between J10 Pins 2 and 3 will connect Pin 43 to VDD for the active hi output enable of a 128K x 16 PROM.

The PROM chip select is connected to the /CSBOOT signal (Pin 112) of U3. At system reset, this signal defaults to decode address %00000 for a block of 1 megabyte, held active for 13 wait states and gated with the processor address strobe. The output enable of the PROM (pin 22) is connected to ground through R8 to allow data to be gated onto the data bus as soon as the /CSBOOT signal goes active. After a system reset, /CSBOOT is configured to have one wait state and to be active only for the address range of the PROM.

Processor RAM (U13 and U23)— The RAMs are used by the processor to store program variables, values and trend data. Each is 128K x 8, arranged to provide 128K x 16 bits of RAM for use by the processor. U3 address lines A17 through A1 are connected to both RAMs' address lines A16 through A0. U3 data bus lines D15 through D8 are connected to U13 data bus lines D7 through D0 for the upper 8 bits of data. U3 data bus lines D7 through D0 are connected to U23 data bus lines D7 through D0 for the lower 8 bits of data.

The active low chip select inputs of U13 and U23 are connected to the CS0 and CS1 chip select outputs of U3. The active high chip select inputs of U13 and U23 are connected to the active low system reset to prevent writing to the RAM while the system power is coming on or while the watchdog reset is active. The output enables of U13 and U23 are connected to digital ground. The write enable inputs of U13 and U23 are connected to the data direction (R/-W) output of U3. At system reset, the RAM chips are disabled and CS0 and CS1 from U3 are disabled. After system reset, CS0 and CS1 are configured to be gated with data strobe output DS from U3.

When the N-3000 is in STANDBY, RAM power is supplied by the backup battery output of the BQ2001. Power is maintained by the N-3000 lead-acid battery and, in the event that the lead-acid battery becomes discharged or is removed, by the lithium backup battery BT1.

Arcnet controller — U6 is the Arcnet controller (COM20020). It is used by the processor to implement the stackbus protocol. It is an 8-bit, memory-mapped device that manages the stackbus communications physical implementation along with the stackbus adapter. It is connected to the upper 8 bits of the processor data bus to allow for byte operations from the processor. The chip select for U6 is processor pin /CS4.

Digital to Analog Converter — DAC U5 is an 8-bit converter used by the processor to control speaker volume. It is a write-only, memory-mapped peripheral connected to the upper 8 bits (D15 through D8) of the processor data bus. It converts the 8-bit data value written into it by the processor to control the amplitude of the square wave generated by processor output OC2. The resultant amplitude controlled square wave is then sent to audio amplifier U4 to drive the 8-ohm speaker. The chip select for U5 is processor pin /CS5.

Analog to Digital Converter — ADC U27 is an 8-bit analog to digital converter used by the processor to measure three different analog voltages. It is a read-only, memory-mapped peripheral connected to the upper 8 bits (D15 through D8) of the processor data bus. The analog voltage values indicate which display board button has been pressed, what the combined voltage of both lithium batteries is, and the value of the analog voltage being supplied from transistor Q10 to the SpO2 module and 5V regulator chips (U17 and U18). The chip select for U5 is processor pin /CS7. The selection of analog voltages to read is controlled by processor outputs PWMA and PWMB which must be set up prior to accessing U27.

Stackbus Adapter — Adapter U14 is an FPGA (field programmable gate array) used by the processor to control the hub functions for both the internal and external stackbus. It also decodes the knob movement as well as providing a 32.679kHz source clock. It is an 8-bit, memory-mapped peripheral connected to the upper 8 bits (D15 through D8) of the processor data bus. The internal stackbus provides the communications for the UIF module and the SpO₂ module. The external stackbus is used to communicate with other instruments when the unit is used in the stack configuration. The chip select for U14 is processor pin /CS3.

Universal Asynchronous Receiver Transmitter — UART U24 is an industry standard 16C550. It is an 8-bit memory-mapped peripheral connected to the upper 8 bits (D15 through D8) of the processor data bus. It contains two 8-byte FIFOs, one for transmit and one for receive, a baud rate generator, and several programmable I/Os for enabling isolated power on the communications module, serial communication handshaking, and alarm active signaling. The chip select for U24 is processor Pin /CS6.

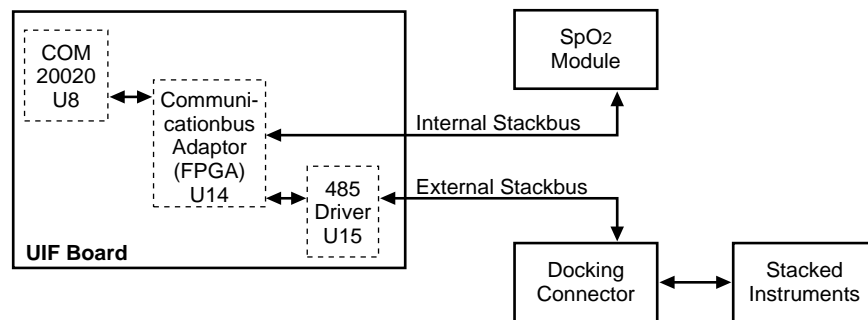


Figure S4-3: Internal/External Stackbus Connections

d. Processor Support ICs

The processor support ICs are used to monitor the processor and its power supply, resetting U3 when necessary, and to sound an alarm using piezo speaker Y1 when the processor appears to be inoperative or when the unit has had an unexpected power loss.

The processor support ICs are watchdog timer U21 and the processor/power fail circuitry consisting of U16, U1, U2, U11, U22, and U29.

Watchdog Timer — Timer U21 ensures that processor U3 does not operate and switches the backup battery power from U20 to the RAMPWR supply when the +5 volt supply is below its lower regulation limit. This chip holds U3 in reset until the power supply is above its lower regulation limit.

The watchdog timer also resets the processor if the processor input signal (CLRWD) is not toggled within a timeout period controlled by the watchdog oscillator circuitry. When the watchdog times out, it generates a signal that causes the piezo power loss alarm speaker to emit a tone. The timeout also causes the display to go blank and generates a reset to U3. The tone continues until the watchdog is cleared due to:

- activity on the CLRWD signal line
- pressing the ALARM SILENCE button
- removing power from the circuit

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Timer U21 also switches the backup battery power from U20 to RAMs U13 and U23, the processor/power fail circuitry, when the +5V supply is below its lower limit.

Processor/Power Fail Circuitry — This circuitry sounds the piezo speaker if the processor fails to operate or the 5V power unexpectedly falls below its lower regulation limit.

e. Connectors

This section describes UIF connectors and pinouts other than the docking connector J13.

J8 — J8 is a 40-pin daughter board connector that interfaces the UIF module to the communications board. This board uses only the first 16 pins on the connector.

Table S4-2: J8 Connector

Pin No.	Pin Description	Input/Output/Power
1	Ground	Power
2	Ground	Power
3	UARTTXD (RS232/422 only)	O
4	Ground	Power
5	UARTRXD (RS232/422 only)	I
6	Internal Stackbus	I/O
7	QData (sub module detection)	I
8	UARTDTR (RS232/422 only)	O
9	Ground	Power
10	VCC	Power
11	VCC	Power
12	VCC	Power
13	VCC	Power
14	Ground	Power
15	External Communications Standby	O
16	UARTDSR (RS232/422 only)	I
17	Not Used	n/a
18	NURSECALL	O
19	Not Used	n/a
20	Ground	Power
21	Interrupt from second COM20020	I
22	Analog power	Power
23	Ground	Power
24	Ground	Power
25	Reset	O
26	DSL (data strobe low)	O
27	SDCK (used for sub module detection)	I
28	Chip select	O
29	Read/Write Strobe	O
30	D14	I/O
31	D12	I/O
32	D15	I/O
33	A1	O
34	D13	I/O
35	A2	O
36	D10	I/O
37	D8	I/O
38	D11	I/O
39	A0	O
40	D9	I/O

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J12, J22 — These are two identical connectors that interface to the SpO₂ module. Power and stackbus signals are sent to these modules. Additionally, a connection between these two connectors allows the modules to communicate without stackbus, if necessary.

Table S4-3: J12, J22 Inter Module Connector

Pin No.	Pin Description	Input/Output/Power
1	Ground	Power
2	VDD	Power
3	Internal stackbus	I/O
4	VDD	I/O
5	Signal line from expansion module to SpO ₂	I/O
6	VDD	I/O
7	Signal line from SpO ₂ to expansion module	I/O
8	Module reset	I/O
9	High voltage power	Power
10	Ground	Power
11	Not used	n/a
12	Ground	Power
13	Not used	n/a
14	Ground	Power

J5 — Connector J5 connects to the display board, which allows the UIF module to control the monitor display. Signals at this connector include power, serial clock and data lines, button signal, and charging battery indicator current.

Table S4-4: J5 Display Connector

Pin No.	Pin Description	Input/Output/Power
1	Power (from switch—controlled by external watchdog)	Power
2	Power (from switch—controlled by external watchdog)	Power
3	Power for green Power On LED	Power
4	Serial clock	O
5	LED drivers latch enable	O
6	Data out	O
7	Power to Battery Charging LED	Power
8	Not used	n/a
9	On button	I
10	Button voltage	I
11	Not used	n/a
12	Charge bus voltage	Power
13	Digital ground	Power
14	Digital ground	Power

J2 — Connector J2 connects the UIF board to the monitor speaker.

Table S4-5: J2 Speaker Connector

Pin No.	Pin Description	Input/Output/Power
1	Differential speaker signal +	I/O
2	Differential speaker signal –	I/O

J3 — Knob connector J3 allows the U3 controller to detect knob movement.

Table S4-6: J3 Knob Connector

Pin No.	Pin Description	Input/Output/Power
1	Digital ground	Power
2	Knob channel B	I
3	VDD	Power
4	Knob channel A	I
5	Chassis (case) ground	Power

S4.2.3 SpO₂ Controller

The central processing unit (CPU) for the SpO₂ Controller PCB is the U1 microprocessor. It contains an 8-channel, 10-bit analog-to-digital converter. Six inputs—ANALOG0 to ANALOG5—are bussed to the analog board interface connector, J4. Of the remaining signals, ANALOG6 is connected to Vcc and ANALOG7 is connected to ground. These analog inputs are used during the POST to verify proper operation.

a. CPU Reset

Voltage monitor U2, shown in the upper left-hand corner of the schematic diagram, generates the reset for U1. Reset is held low until Vcc raises above 4.6 volts. After Vcc is above 4.6 volts, reset is tri-stated and pulled high by R10. Note: L1, L2, and L3 provide filtering for Vcc.

b. Program Memory (EPROM)

The program memory chip, U4, provides the SpO₂ controller board with 128K bytes of memory. This program boot ROM memory can be expanded up to 256K bytes. The CSBOOT signal from U1, which is configured for 16-bit memory access, provides the enable signal for U4. After system software comes on, or is booted up, CSBOOT is configured for a start address of 0, a block length of 256K bytes, both read and write access, and gated with AS. This configuration provides a program memory range of 00000h through 3FFFF.

The number of wait states needed before the CSBOOT signal is generated depends upon the U1 clock speed and the speed at which U4 can successfully perform its functions. With the N-3000, the number of wait states must be set to 1, based upon a CPU clock speed of 16.0 MHz, maximum, and the U4 access time of 150ns, maximum.

Resistor R22 pulls the U4 OE signal state to low during normal operation. If this signal state is high, the U4 output is disabled.

c. RAM Memory

The U5 RAM chip provides the SpO₂ Controller board with 128K bytes of memory. The U1 CS0 provides the chip enable signal for U3.

The U3 hardware has an 8-bit wide data path. After boot up, CS0 is configured as a chip select with a start address of 40000h, block length of 128K, 8-bit port, both bytes access, both read and write access, and gated with AS. This configuration gives a data memory range of 40000 through 5FFFF.

The number of wait states to generate depends upon the U1 clock speed and the U3 access speed. The number of wait states for CS0 is set to 0, based on a U3 access time of 85ns, minimum.

d. Stackbus

The SpO₂ controller board also communicates with other boards within the N-3000 via the stackbus. The stackbus is controlled by the COM 20020 Arcnet controller chip, U6, which is enabled by U1 CS1.

CS1 must be configured as a chip select with a start address of 60000h, block length of 2k, 8-bit port, both bytes access, both read and write access, and gated with AS. This configuration maps the stackbus in the memory range of 60000h through 607FFh.

The number of wait states to generate depends on the U1 clock speed. The number of wait states for CS1 must be set to 2, based upon a CPU clock speed of 16.0 MHz.

e. Programmable Clock

The clock frequency on the SpO₂ controller board is programmed via software. The clock signal is labeled CTRL_CLK. The clock circuitry consists of U7 and U10. One half of U7 takes a 20 MHz input and produces three output frequencies: 10 MHz, 2.5 MHz, and 1.25 MHz. The 10 MHz frequency is the clock rate of the programmable down counter, U10. The second half of U7 takes the terminal count (TC) output of U10 and converts it to a 50% duty cycle square wave.

The frequency of CTRL_CLK is controlled by an 8-bit number. The bits of this number are split between two output ports. The lower 5 bits of the number are programmed on the lower 5 bits of port C. The upper 3 bits of the number are programmed on the upper 3 bits of port E.

The formula for the CTRL_CLK frequency is: $\text{frequency} = 5\text{MHz} / (1 + \text{TIME})$, where TIME is the 8-bit number output by the CPU. TIME has a valid range of 1-255. The circuit provides an adjustment range of 19.531 kHz to 2.5 MHz.

The CTRL_CLK signal is input back to U1 Pin 16. During the POST routine, this pin is used to monitor the programmable clock hardware output to verify performance.

f. Intermodule Connector

The SpO₂ controller board is connected to the UIF board via the J1 intermodule connector. The UIF board provides power to the SpO₂ controller. Stackbus and module synchronization lines are also routed through J1.

S4.2.4 Communications Submodule

The communications submodule contains circuitry for allowing 1500V isolated asynchronous serial RS232 or RS422 communications between the N-3000 UIF module and a host computer, a 1500V isolated nurse call signal that operates whenever an alarm condition exists, or a 1500V isolated 3.3V power source for powering remote external serial equipment.

Signals that originate on the UIF board include:

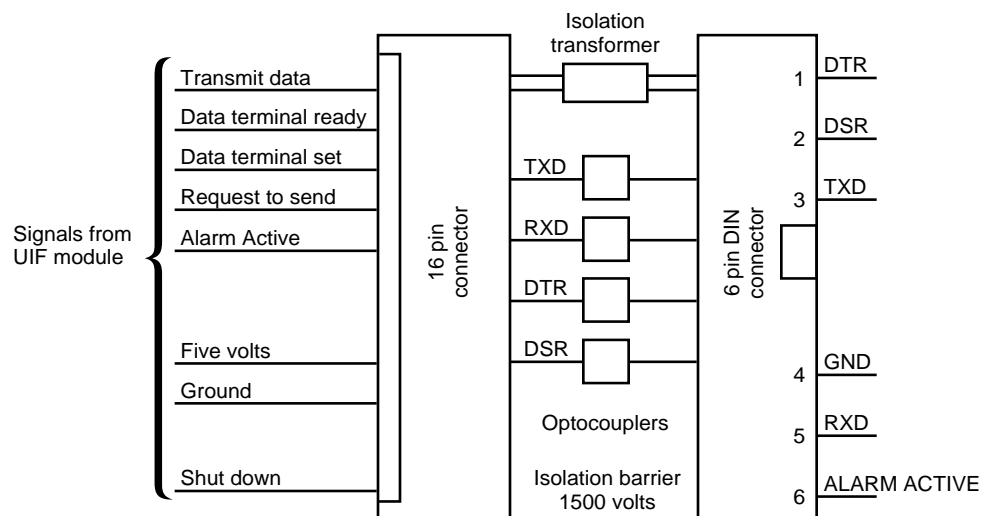
UARTTXD	Transmit data from UART
UARTRXD	Receive data to UART
UARTDTR	Data terminal ready from UART
UARTDSR	Data set ready to UART
ALARMACTIVE	Prog. I/O from UART
Shutdown	Prog. I/O from UART

Connector J5 contains the signals for communicating with the UIF board (J8), as detailed in Table S4-2.

There is an auxiliary connector, J2, on the communications PCB for future expansion.

a. Serial Communications

Serial communications are available only when the SPS power supply is connected to the N-3000 docking connector and plugged into an AC outlet. When the UIF processor detects that CHARGEbus is available, it enables isolation transformer driver U1 (MAX253). This creates power for circuitry on the isolated (host computer) side of the module. Transmit and Receive data cross the barrier through optical isolators U5 and U3 (6N136). CTS and RTS signals cross the barrier through optical isolators U4 and U2 (4N26).



Maximum baud rate: 19.2K

Figure S4-4: Communications Submodule Block Diagram

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Selecting RS232 serial signaling is accomplished by moving switches S1,S3,S5,S7 on SW1 and SW2 to the on position and switches S2,S4,S6,S8 to the OFF position. This enables U9 and disables U10. With RS232 selected, J1 has the following pinout:

- 1 DTR
- 2 DSR
- 3 TXD
- 4 GND
- 5 RXD
- 6 Nurse Call/3.3V

Selecting RS422 serial signaling is accomplished by moving switches S2,S4,S6,S8 on SW1 and SW2 to the on position and switches S1,S3,S5,S7 to the OFF position. This enables U10 and disables U9. With RS422 selected, J1 has the following pinout:

- 1 TXD-
- 2 RXD-
- 3 TXD
- 4 GND
- 5 RXD
- 6 Nurse Call/3.3V

b. Alarm Active/3.3V Power

Isolated alarm active or 3.3 volt power is selectable as a 500mA fused output on J1 Pin 6. Placing switch block SW3, S1 to the on position, and S2,S3,S4 to the OFF position, will select the alarm active signal on J1 Pin 6. The alarm active signal provided is a normally open relay that shorts Pin 6, J1 to Pin 4, J1 signaling an alarm event.

To select isolated 3.3 volt power, place switch SW3 S1 to the OFF position and S2,S3,S4 to the on position. This provides up to 100mA of 3.3 volt power.

S4.2.5 Display Board

The N-3000 display board is the assembly that contains the front-panel display for the monitor. The display board is connected to and controlled by the UIF module. The display board block diagram is shown in Figure S4-5.

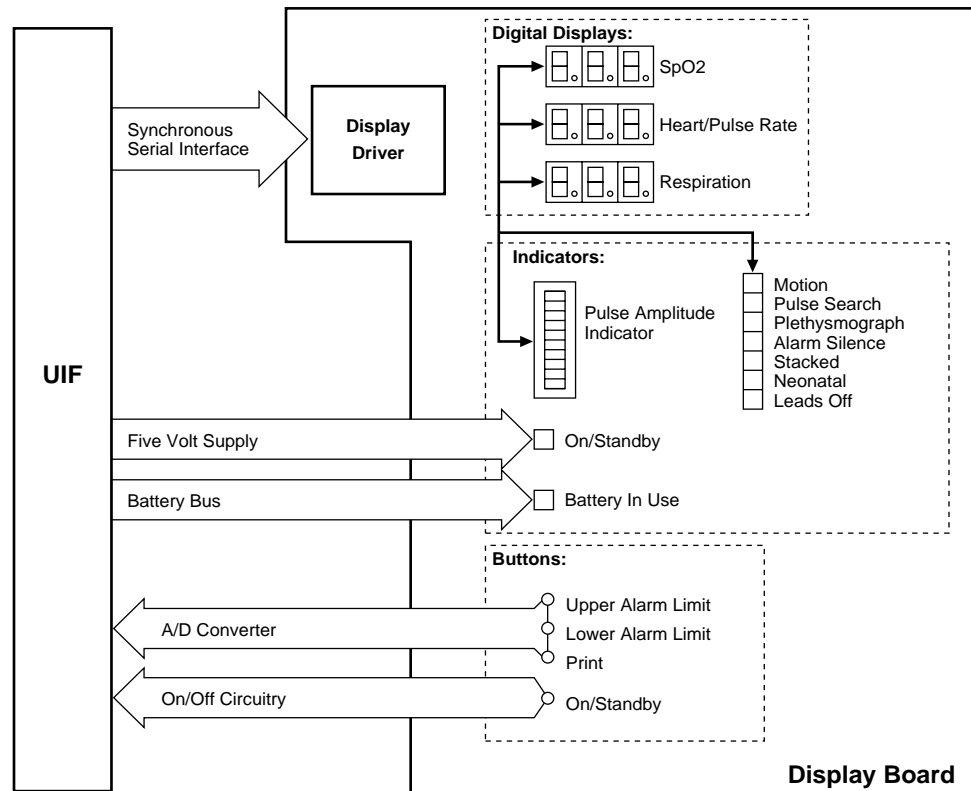


Figure S4-5: Display Board Block Diagram

The display driver ICs consist of U1, U2, and U3, which use a three-wire serial interface connect to the CPU (U3) on the UIF module. The three drivers used on this module are cascaded together and require that the host processor write 48 bits (16 x 3) to the board per each display update.

The front-panel POWER LED (DS23) is lit whenever the monitor power supply is on. Note that the drivers do not provide power to light the BATTERY CHARGING indicator; current for this LED is provided by the UIF module.

There are four buttons on the display panel: the ON/STANDBY button (SW2) is connected directly to the UIF module. The other three—UPPER ALARM LIMIT (SW1), LOWER ALARM LIMIT (SW3), and PRINT (SW4)—are resistor-weighted and attached via one signal line to an A/D channel of the UIF module. U4 is a drain device used to guarantee a certain resistance value when a button is pressed.

Technical Supplement

The J1 connector pinouts are as follows:

1	+5V power for display drivers	8	NC
2	+5V power for display drivers	9	ON button signal, ONBUTTON
3	+5V power for green LED, GREENPWR	10	Button signal, BUTRES
4	Serial clock to display drivers, SERCLK	11	NC
5	Load data to display drivers, LED1EN	12	NC
6	Serial data to display drivers, SERDATA	13	Ground
7	Current source to battery charging indicator, CHRGPWR	14	Ground

S.5 SCHEMATIC DIAGRAMS

The following part locator diagrams and schematics are included in this section:

Figure	Description
Figure S5-1	SpO ₂ PCB Part Locator Diagram
Figure S5-2	UIF PCB Part Locator Diagram
Figure S5-3	SpO ₂ Controller PCB Part Locator Diagram
Figure S5-4	Communications PCB Part Locator Diagram
Figure S5-5	Display PCB Part Locator Diagram
Figure S5-6	SpO ₂ Schematic Diagram
Figure S5-7	UIF Schematic Diagram
Figure S5-8	SpO ₂ Controller Schematic Diagram
Figure S5-9	Communications Schematic Diagram
Figure S5-10	Display Schematic Diagram
Figure S5-11	Lower Docking Connector Schematic Diagram

EXHIBIT 6



OPERATOR'S MANUAL

Oxinet[®] II Monitoring System

Nellcor Puritan Bennett Inc. is an affiliate of Tyco Healthcare Inc. *Nellcor*, *Nellcor Puritan Bennett*, *Nellcor Symphony* and *Oxinet* are trademarks of Nellcor Puritan Bennett Inc.

To obtain information about a warranty, if any, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative.

Covered by one or more of the following U.S. Patents and foreign equivalents:
4,621,643; 4,653,498; 4,700,708; 4,770,179; 4,869,254; 4,928,692; 4,934,372; 5,078,136;
5,351,685; 5,368,026; Re. 35,122.

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SAFETY INFORMATION

Warnings
Cautions

WARNINGS

WARNING: Explosion hazard. Do not use the central station or the bedside station in the presence of flammable anesthetics.

WARNING: The *Oxinet*[®] II monitoring system is to be operated by qualified personnel only. Before use, carefully read this manual, operator's manuals, directions for use, all precautionary information, and specifications for the NPB-290, NPB-295, N-395, N-595, N-3000, the N-3100, N-3200, and accessories. The user must check that the equipment functions safely and see that it is in proper working condition before being used.

WARNING: The components of the *Oxinet II* monitoring system are intended only as an adjunct in patient assessment. The system must be used in conjunction with clinical signs and symptoms.

WARNING: Do not expose any components of the *Oxinet II* monitoring system to extreme moisture levels such as rain. Such exposure may cause incorrect or inaccurate performance, or device failure during or after exposure.

WARNING: The central station is not to be used in mobile environments.

WARNING: Patient safety could be compromised if the central station is used as a personal computer while patients are being monitored. The central station is to be used for patient monitoring only.

WARNING: Patient safety could be compromised if the DOS function is used while patients are being monitored. The DOS function stops all monitoring functions of the *Oxinet II* monitoring system. The DOS function should only be used by the system administrator or by qualified personnel.

WARNING: Patient safety could be compromised if any unauthorized modifications are made to software or hardware at the central station. Any unauthorized change or addition of software or hardware to the *Oxinet II* monitoring system may affect patient safety or efficacy.

WARNING: The *Oxinet II* monitoring system is intended to monitor patients. It is not a diagnostic device. Any alarm or abnormal indication displayed at the central station should be reviewed by qualified clinical or technical personnel to determine if an appropriate diagnostic procedure should be initiated.

WARNING: Electric shock hazard. External covers and panels are to be removed only by qualified service personnel. There are no user-serviceable parts inside.

WARNING: Do not use any components of the *Oxinet II* monitoring system that are damaged.

WARNING: Do not use any component of the *Oxinet II* monitoring system with a frayed or damaged power supply cord.

WARNING: For USA locations, do not connect any components of the *Oxinet II* monitoring system to an electrical outlet controlled by a wall switch.

WARNING: When the Discharge function is initiated at the central station or when the New Patient/Neonatal button on a N-3000 monitor is pressed and held for 3 seconds, the discharge function is initiated at the central station. All patient information and all trend data for the patient stored in the central station will be *permanently deleted*.

WARNING: System default, date, and time settings are selected and set by the system administrator. For optimal patient safety, system default, date, and time settings should be reviewed periodically.

WARNING: Do not tape or adhere anything to the face of the touchscreen monitor. The central station may receive a false touch signal.

WARNING: When using the N-3000, the central station displays the operating mode of the N-3000 only (neonatal or adult-pediatric). When using an N-3100 and an N-3000 at the bedside, verify that both monitors are set to the desired operating mode (Adult-pediatric or Neonatal) before using the bedside station for patient monitoring.

WARNING: The power cord supplied with the central station computer is designed to reduce EMI emissions. Use of this cord is required to ensure compliance with Class B performance.

Alarms

WARNING: Patient safety could be compromised if the alarm silence function at the central station is set to OFF for any alarm and the central station is not being monitored visually. When alarm silence is set to OFF, the only means of alarm indication is visual. Before using the *Oxinet II* monitoring system, verify that patient alarms are monitored visually if an alarm silence function is set to OFF. Do not silence audible alarms at the central station or at the bedside station or decrease their volume if patient safety could be compromised.

CAUTIONS

Caution: Do not immerse any component of the central station in liquid or use caustic or abrasive cleaners. Do not spray or pour any liquid on the central station or its accessories. Do not allow any liquid to come in contact with the power connector, controls, or switches. Do not allow any liquid to penetrate connectors or openings in the chassis.

Caution: Do not put the computer, touchscreen monitor, or uninterruptible power supply inside a cabinet or other closed space where air cannot freely flow around these components.

INTRODUCTION

Intended Use
About this Manual

INTENDED USE

The *Oxinet II* monitoring system consists of a central monitoring station (central station) and one or more Nellcor bedside monitors (bedside station) consisting of an NPB-290 pulse oximeter, NPB-295 pulse oximeter, N-395 pulse oximeter, N-595 pulse oximeter, or N-3000 pulse oximeter and, optionally, an N-3100 noninvasive blood pressure monitor, the N-3200 display/printer, or both.

The NPB-290, NPB-295, N-395, N-595, and N-3000 monitor SpO₂ and pulse rate. The N-3000 with ECG capabilities also monitors ECG and heart rate. The N-3000 with ECG and respiration capabilities also monitors respiration rate. The N-3100 monitors systolic, diastolic and mean arterial blood pressure, and derives pulse rate at the time of the blood pressure measurement.

The *Oxinet II* central station communicates with all bedside stations in the system either through a radio-link connection or through a hard-wired connection.

The *Oxinet II* monitoring system is intended to be used to supplement the safe operation of disperse or remotely located Nellcor bedside monitors. In radio-link systems, the *Oxinet II* monitoring system allows simultaneous remote monitoring of up to 30 bedside stations from a central station. In hard-wired systems, up to 16 bedside stations can be monitored. The central station displays bedside station monitor settings, monitor alarm status and physiological patient information as communicated from the bedside monitors.

The *Oxinet II* monitoring system is not intended to replace on-hand competent medical staff in monitoring for bedside station alarms but is intended to provide support by notifying staff in the event of alarm conditions or monitor changes.

The *Oxinet II* monitoring system provides a convenient way to monitor many remote bedside stations at a central station.

The central station is intended to be used in an environmentally controlled hospital setting.

WARNING: The components of the *Oxinet II* monitoring system are intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: Patient safety could be compromised if the central station is used as a personal computer while patients are being monitored. The central station is to be used for patient monitoring only.

WARNING: Patient safety could be compromised if the DOS function is used while patients are being monitored. The DOS function stops all monitoring functions of the *Oxinet II* monitoring system. The DOS function should only be used by the system administrator or by qualified personnel.

WARNING: The *Oxinet II* monitoring system is intended to monitor patients. It is not a diagnostic device. Any alarm or abnormal indication displayed at the central station should be reviewed by qualified clinical or technical personnel to determine if an appropriate diagnostic procedure should be initiated.

ABOUT THIS MANUAL

This manual explains how to set up and use the *Oxinet II* monitoring system. Important safety information is contained in the *Safety Information* section preceding this introduction. **Read the entire *Safety Information* section before you operate the *Oxinet II* monitoring system.** Important safety information is also presented throughout this manual where appropriate. When setting up and operating the NPB-290, NPB-295, N-395, N-595, N-3000, N-3100, or N-3200 instruments at a bedside station, it is important that you are familiar with safety information presented in the operator's manual and directions for use for each of those instruments.

In addition to the safety information section and this introduction, this manual includes the following sections:

- *Equipment and Accessories* identifies and describes the components of the *Oxinet II* monitoring system.
- *Controls, Indicators, and Screens* describes the central station, identifies all controls, indicators, and symbols, and explains their function.
- *System Configuration* explains how to set up system default settings and how to perform system administration functions.
- *Bedside Station Setup* explains how to set up the bedside station and how to connect the remote radio transceiver or the hard-wire cable.
- *Central Station Hookup* explains how to connect the central station components at installation and after moving.
- *Central Station Setup* explains how to set up and connect the components of the central station and how to connect the central station radio-link antennas or the hard-wired cabling.
- *Start-up and Use* explains how to operate the central station and how to turn on the bedside station.
- *Troubleshooting and Maintenance* provides information about servicing the central station and data communication and obtaining technical assistance.
- *Specifications* lists technical specifications for the remote radio transceiver at the bedside station and the components of the central station. Minimum requirements are also included for a laser printer if a laser printer is required and provided by your facility. Regulatory agency notices are also provided in this section.

The most current version of this manual is available online at

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

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EQUIPMENT AND ACCESSORIES

System Overview
 Central Station
 Bedside Station
 Data Communication Configuration

SYSTEM OVERVIEW

The major components of the *Oxinet II* monitoring system are the central station, the bedside stations, and one of two data communication configurations. The *Oxinet II* monitoring system components are illustrated in Figure 1 and described in the following paragraphs.

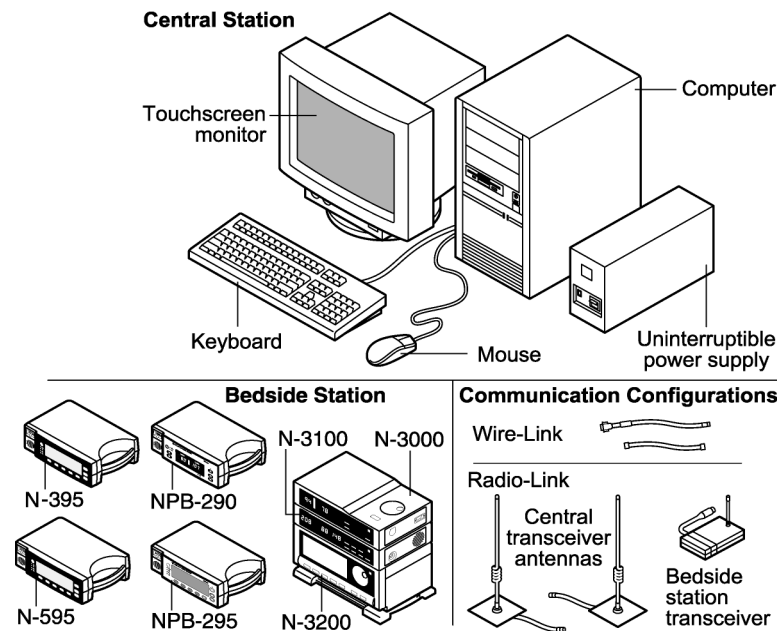


Figure 1: Oxinet II Monitoring System

Patient data is converted to a digital format at each bedside station and is transmitted to the central station through a radio-link or a hard-wired connection.

CENTRAL STATION

Refer to Figure 1. The central station consists of the computer, the touchscreen monitor, the keyboard, the mouse, uninterruptible power supply, optional thermal printer (not shown) and an optional laser printer (not shown). These components are described in the following paragraphs.

The *Oxinet II* system can be configured in one of three general ways. One configuration is as a hard-wired system where an individual hard-wire connection is made between each bedside station and the central station. There are two radio-link configurations: one uses a spread-spectrum, frequency-hopping design and the other uses a fixed-frequency design where the link between each bedside station and the central station is made through individual bedside station radio frequency transceivers and one or more central radio frequency transceivers.

Computer

The computer is the primary component of the central station in the operation of the *Oxinet II* monitoring system. Patient data from the bedside stations is processed by the computer for display on the touchscreen monitor. The computer works very much like a typical personal computer (PC) and is housed in a standard mid-tower enclosure. It contains a motherboard, a 3.5-inch floppy disk drive, a hard disk drive, a video controller circuit board, and circuits for interfacing with the keyboard and the mouse. The computer may also contain an optional thermal printer. The touchscreen monitor controller circuit board is also contained in the computer. In radio-link systems, the computer also contains a sound board and one to three central radio transceivers. In hard-wired systems, the computer also contains one or two multi-I/O boards and one or two I/O extension boards.

Touchscreen Monitor

The *Oxinet II* monitoring system uses a touchscreen monitor with a color display. The operator touches the face of the screen to initiate or control an *Oxinet II* monitoring system function.

WARNING: Do not tape or adhere anything to the face of the touchscreen monitor. The central station may receive a false touch signal.

Uninterruptible Power Supply

An uninterruptible power supply (UPS) is used to provide power for the computer and the touchscreen monitor if primary power is lost. The UPS provides time to shut off the central station and make other arrangements for patient monitoring.

Mouse

The mouse is used to move a pointer on the monitor screen to a desired location such as over a key, button, waveform or on-screen help index topic. The mouse has two buttons. Positioning the pointer and clicking either mouse button is the equivalent of touching the face of the touchscreen monitor at the location of the key, button, waveform, or on-screen help index topic.

Keyboard

The keyboard connected to the computer is a standard 101-key PC-type keyboard used to enter alphanumeric patient data. The keyboard does not have to be connected to the computer to operate the *Oxinet II* monitoring system. The operator can use an on-screen keyboard where keyboard keys are pressed by touching keys displayed on the monitor or by clicking the keys with the mouse.

Thermal Printer (Optional)

Some units may be equipped with a thermal. The thermal printer is connected to the sound card in the radio-link system. The thermal printer provides digital data and waveform printing during an alarm condition or at the request of the operator. The waveform includes the 10-second period before and after the print initiation and the most current digital data for the patient.

Laser Printer (Optional)

An optional laser printer (not shown in Figure 1) can be connected to the computer to provide printouts of patient data and system status data. The central station is not supplied with a printer. The printer must be provided by the facility. See the *Specifications* section, page 111, for minimum laser printer requirements.

BEDSIDE STATION

Every bedside station includes an NPB-290, NPB-295, N-395, N-595, or an N-3000 pulse oximeter. An N-3100 noninvasive blood pressure monitor and/or N-3200 printer can also be stacked with an N-3000 at a bedside station. These instruments monitor and process patient parameters and convert the measured parameters to digital data. This digital data is transmitted to the central station. All bedside station equipment must be powered by AC power to communicate with the *Oxinet II* system.

DATA COMMUNICATION CONFIGURATION

In radio-link systems, each bedside station and the central station communicate via a radio-link data communication configuration to send digital patient data from the bedside station to the central station for processing and display.

An external radio transceiver with a built-in antenna is connected to the NPB-290, NPB-295, N-395, N-595, or mounted on the N-3000 at each bedside station in an *Oxinet II* monitoring system installation. The remote transceiver is connected to the serial data communication port on the back of the NPB-290, NPB-295, N-395, N-595, or N-3000. Each transceiver exchanges digital data with the central station and operates in the frequency range of 902 MHz to 928 MHz.

A frequency-hopping radio-link configuration uses a single central radio transceiver printed circuit board at the central station that is connected to antennas that are mounted in the ceiling. The antenna base plate is mounted inside the ceiling and the antenna hangs down from the ceiling.

A fixed-frequency radio-link configuration uses one or more central radio transceiver pcbs and antennas at the central station.

In hard-wired systems, each bedside station and the central station communicate over hard-wired connections. Digital patient data is transmitted over the hard-wired connection from the bedside station to the central station for processing and display.

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CONTROLS, INDICATORS, AND SCREENS

System Overview
Touchscreen Monitor
Screen Overview
Description of Screens
Date/Time Display
Alarm Indications

SYSTEM OVERVIEW

This section provides general information about *Oxinet II* monitoring system controls, indicators, and screens. Detailed *Oxinet II* system operating instructions are contained in the *Start-Up and Use* section.

Detailed controls, indicators, setup, start-up, and use instructions for the monitors at the bedside station can be found in the operator's manual for the NPB-290, NPB-295, N-395, N-595, N-3000, and N-3100. Instructions for using and connecting the N-3200 display/printer are found in the N-3200 operator's manual.

TOUCHSCREEN MONITOR

The *Oxinet II* monitoring system is operated by touching keys, buttons, waveforms or on-screen help index topics displayed on the touchscreen monitor. A mouse can be used instead of touching the screen by positioning the screen pointer on the key, button, waveform, or on-screen help index topic and pressing either mouse button. Throughout the rest of the text describing operation of the *Oxinet II* system, this action is referred to as *clicking*. An external keyboard can also be used to enter patient data or the mouse can be used to click screen keys.

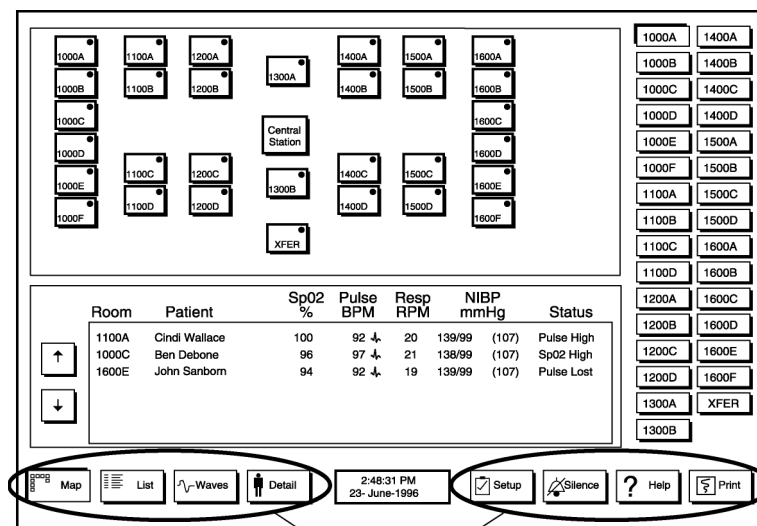
WARNING: Do not tape or adhere anything to the face of the touchscreen monitor. The central station may receive a false touch signal.

SCREEN OVERVIEW

The upper left area of each central station display contains the operational screens that are described in *Description of Screens* on page 20. Each display screen always has two types of buttons used for most *Oxinet II* monitoring system operations—the *function buttons* and the *bed buttons*. Function buttons and bed buttons are individually described below.

Function Buttons

There are eight function buttons displayed at the bottom of every central station screen (see Figure 2). Before a function button is clicked and selected, it appears as though it is up or out and the letters on the button are white. When a function button is clicked and selected, the button appears as though it is pressed down and the letters on the button are black. Detailed instructions for the use of the function buttons are contained in the *Start-Up and Use* section.



Function buttons

Figure 2: Function Buttons

Map Function Button



Click the Map function button to display the Map screen.

List Function Button



Click the List function button to display the patient List screen.

Waves Function Button



Click the Waves function button to display up to eight plethysmograph or ECG waveforms simultaneously on the Waves screen. Then any one of five pages of up to eight waveforms can be selected.

Detail Function Button



Click the Detail function button to display an individual patient's measured digital parameters and their plethysmograph or ECG waveform on the Patient Detail screen. Data is displayed for the patient whose bed button is selected.

Setup Function Button



Click the Setup function button to display the Patient Setup screen. Data is displayed for the patient whose bed button is selected.

Silence Function Button



To silence an individual audible alarm at the central station for a preset amount of time, click the flashing bed button followed by the Silence function button.

Help Function Button



Click the Help function button to display helpful information about the currently displayed screen or to select a topic about which you need help or information.

Print Function Button



Click the Print button to print patient data on a laser printer connected to the central station computer. Data is printed for the patient whose bed button is selected.

Bed Buttons

The *bed buttons* are located along the right side of every central station screen (see Figure 3). A bed button is displayed for each bed that is in the area being monitored by the *Oxinet II* system with the number of the bed shown on the button. There can be from one to 31 bed buttons displayed depending on the *Oxinet II* system configuration, including a bed that is used during transfers. The left column of bed buttons is for 1 to 16 beds and the right column of bed buttons is for 17 to 31 beds. These buttons also provide individual visual bed alarm or operating indications and are used for silencing audible alarms at the central station.



(Normal)

Click a bed button to make it the active bed for further operations or for silencing an individual alarm for that bed. Only one bed button may be selected at a time.

The letter “S” is displayed on a bed button when a bed is in standby.

(Standby)

A silence symbol, which is a bell with a diagonal line through it, is displayed on a bed button when an alarm is silenced for that bed. The silence symbol flashes whenever one or more central station patient alarm settings have Audible set to OFF.

(Silenced)

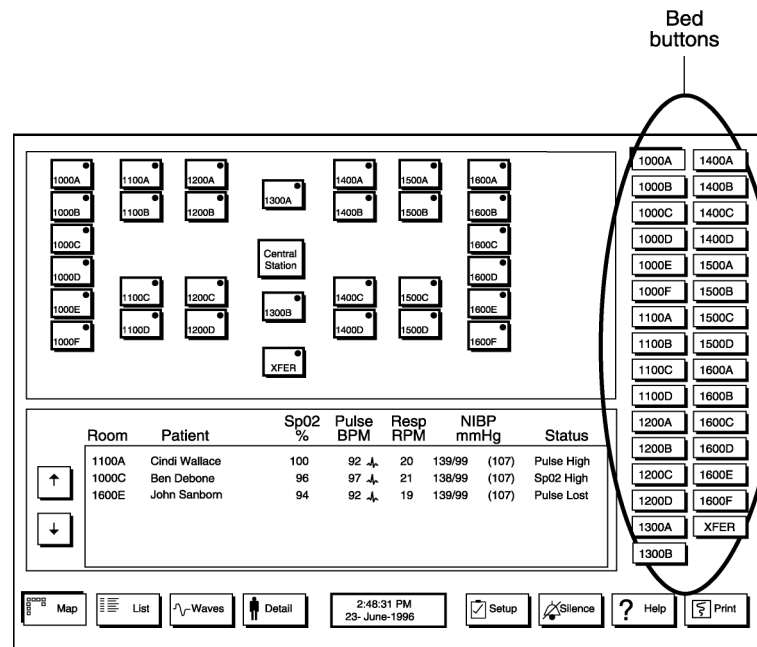


Figure 3: Bed Buttons

Other Screen Buttons

Some screens have additional buttons or keys that are clicked to perform system operations on those screens. The function of these buttons or keys is described in the *Start-Up and Use* section.

DESCRIPTION OF SCREENS

Screen Overview

There are six primary screens used in the operation of the *Oxinet II* monitoring system. They are the Map screen, the List screen, the Waves screen, the Patient Detail screen, the Setup screens, and the Help screens. The Patient Alarm List is shown on all these screens except the Waves screen. A basic description of each screen and the Patient Alarm List are contained in the following paragraphs. Detailed operating instructions for the screens and for the *Oxinet II* monitoring system are contained in the *Start-Up and Use* section.

Note: Whenever a non-invasive blood pressure (NIBP) value of “-1” is shown in any patient data display, it is an indication that patient data is not available from N-3100 at the bedside station for that patient. Dashes are also used to indicate that patient data is not available.

A flashing alarm silence symbol (a bell with a diagonal line through it) is displayed on a bed button and in the message area of the Patient Detail screen, whenever one or more central station patient alarm settings has Audible set to OFF.

Patient Alarm List

A typical Patient Alarm List is shown in Figure 4. The Map screen, Patient Detail screen, Patient Setup screen and Help screens contain a scrollable list of all current patient alarms. This list is displayed at the bottom of each of these screens above the function buttons. Only beds currently in an alarm state are displayed. Each entry on the list shows the patient's bed number, name, current measured parameters, and an alarm or status message. The most recent alarm detected by the *Oxinet II* monitoring system appears at the top of the list.

In the case of simultaneous alarms for a patient, the highest priority alarm appears in the list. When there are multiple simultaneous alarms of equal priority, display of the alarm messages cycles at 1-second intervals.

Note: The Patient Alarm List displays only six alarms even when more than six beds are in an alarm state. There is no indication in the Patient Alarm List that there are more entries on the list.

The bed buttons provide an indication of all beds that are in an alarm state. When more than six beds are in an alarm state, use the up-arrow or down-arrow buttons to the left of the list to scroll the list up or down.

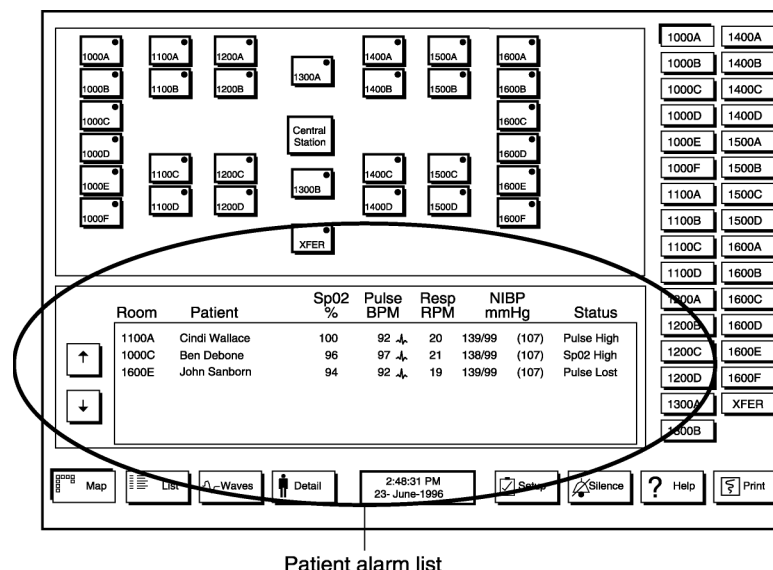


Figure 4: Typical Patient Alarm List

Map Screen

A typical Map screen is shown in Figure 5. The Map screen is the initial screen that is displayed when the *Oxinet II* monitoring system is first turned on and initialization is complete. The Map screen is also displayed when the Map function button is clicked. The map is customized in system setup by the system administrator to look like the floor plan of the area monitored by the *Oxinet II* monitoring system, showing bed locations relative to the central station. The central station is represented by a box containing the words *Central Station*.

Each bed is represented by a box that contains the room or bed number and a colored dot. When a room contains more than one

monitored bed, each bed is represented by a different box containing a unique bed number. The presence and color of this dot indicate the standby and alarm status of monitored patient conditions as described in the *Start-Up and Use* section. This screen also contains the Patient Alarm List.

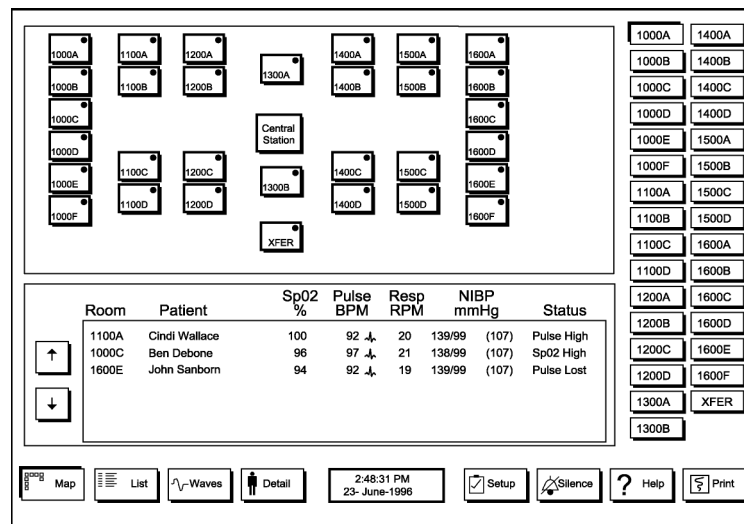


Figure 5: Typical Map Screen

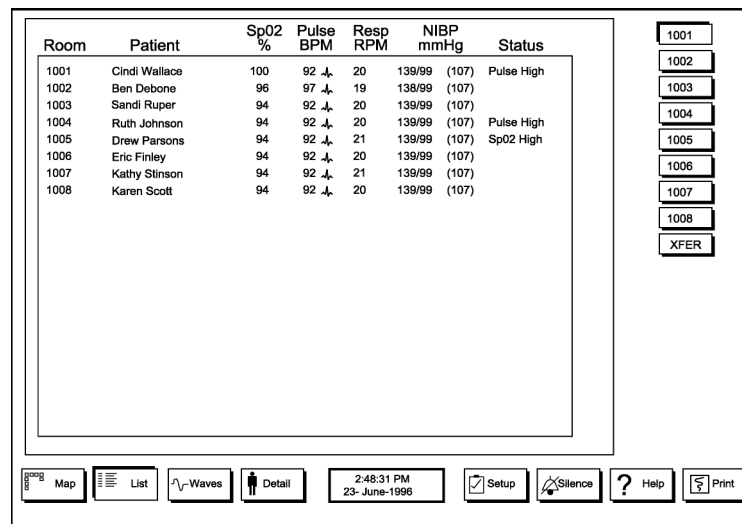
List Screen

A typical List screen is shown in Figure 6. The List screen is displayed when the List function button is clicked. Data for all monitored patient beds is displayed, listed in the same order as the bed buttons. The number in the Room column corresponds to the patient's bed number.

Besides the room number and the patient's name, this list provides the current available monitored values for SpO₂, pulse rate, respiration rate and blood pressure from the bedside station. The status column shows any current alarm status. The highest priority alarm message is displayed.

If there are two or more alarm messages of equal priority, the message display cycles through the messages at 1-second intervals. The word *Standby* is shown in the status column when the bed is in standby. The Patient Alarm List is not displayed on the List screen.

Note: Whenever an NIBP blood pressure value of “-1” is shown in any patient data display, it is an indication that patient data is not available from the N-3100 at the bedside station for that patient. Dashes are also used to indicate that patient data is not available.



Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1002	Ben Debone	96	97 ↓	19	138/99 (107)	
1003	Sandi Ruper	94	92 ↓	20	139/99 (107)	
1004	Ruth Johnson	94	92 ↓	20	139/99 (107)	Pulse High
1005	Drew Parsons	94	92 ↓	21	139/99 (107)	SpO2 High
1006	Eric Finley	94	92 ↓	20	139/99 (107)	
1007	Kathy Stinson	94	92 ↓	21	139/99 (107)	
1008	Karen Scott	94	92 ↓	20	139/99 (107)	

1001

1002

1003

1004

1005

1006

1007

1008

XFER

Map

List

Waves

Detail

2:48:31 PM
23-June-1996

Setup

Silence

Help

Print

Figure 6: Typical List Screen

Waves Screen

A typical Waves screen is shown in Figure 7. The Waves screen is displayed when the Waves function button is clicked. Each Waves screen displays a maximum of eight individual patient plethysmograph or ECG waveforms.

Below each waveform, current available monitored digital values for SpO₂, pulse rate, blood pressure, and respiration rate are also displayed. Individual waveform areas must have a bed assigned before a waveform is displayed. There are five waveform pages available, each with eight waveform areas that can be selected. The Patient Alarm List is not displayed on the Waves screen.

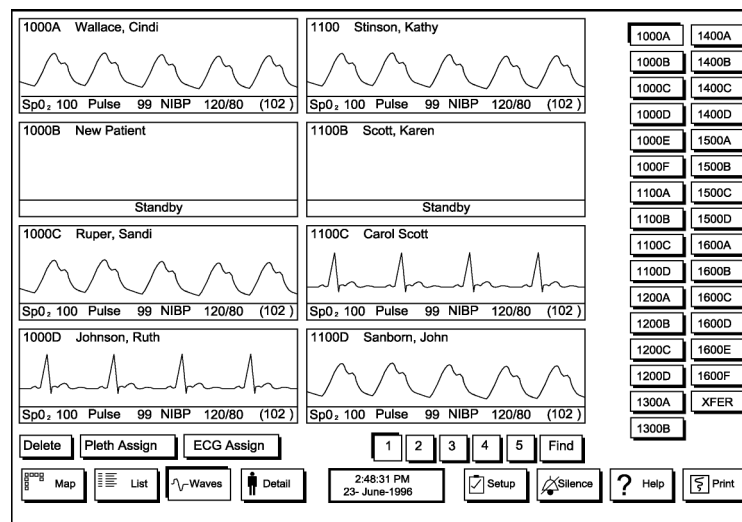


Figure 7: Typical Waves Screen

Patient Detail Screen

A typical Patient Detail screen is shown in Figure 8. When the Detail function button is clicked, the Patient Detail screen is displayed for the patient assigned to the currently selected bed button. Current digital values for patient SpO₂, pulse rate, respiration rate, and blood pressure, and the plethysmograph or ECG waveform are displayed for the patient assigned to the bed button selected.

Note: Current digital values and waveforms displayed are limited to the functions of the bedside monitor being used.

Patient trend data can also be observed by pressing the Trends Graph button or the Trends Table button on the Patient Detail Screen. Use of the Patient Trends screens is described in *Start-Up and Use*.

The Patient Detail screen also contains the Patient Alarm List. However, the Patient Alarm List is not displayed when viewing the Trends Graph and Trends Table screens. Thermal printer or laser printer printouts of the displayed waveform can be initiated from this page.

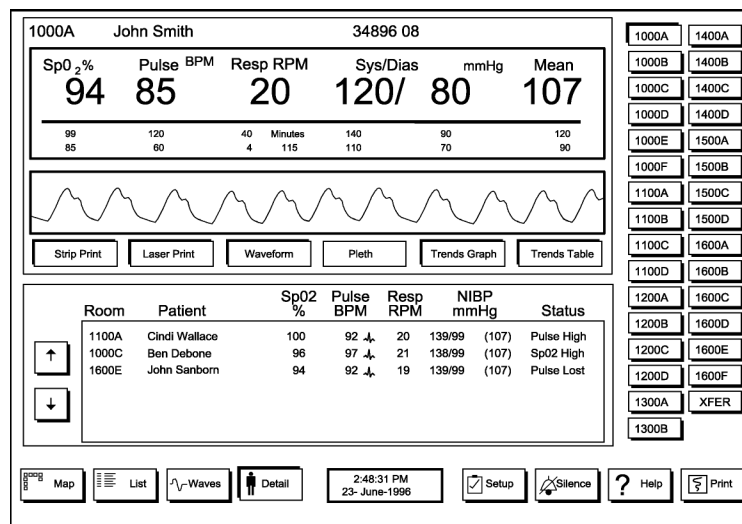


Figure 8: Typical Patient Detail Screen

Note: Whenever any patient alarm Audible setting is set to OFF during patient setup, the message display on the Patient Detail screen constantly displays a flashing alarm silence symbol.

Patient Setup Screen

The Patient Setup screen is shown in Figure 9. The Patient Setup screen is displayed when the Setup function button is clicked. The bed button that is clicked and selected is the bed selected for setup. If patient data is already entered, the patient's bed number and name are displayed at the top of the screen.

The Patient Setup screen is used to set the channel standby state, set the channel gain for the patient's plethysmograph waveform and set the scale for the patient's ECG waveform. This screen is also used for transferring a patient from one bed to another, and for discharging a patient.

This screen also provides access to other screens for admitting a new patient, changing patient data, and for setting patient-alarm and print-on alarm settings. Detailed instructions for using the Patient Setup screen can be found in the *Central Station Setup* section. The System settings button at the top of the screen is used for displaying information for system setup by the system

administrator. The Patient Setup screens also contain the Patient Alarm List.

1000F Jones, David 789-01-2345
 Settings: ☐ Patient ☐ System

Buttons: Admit, Standby, OFF, Discharge, SpO₂ Gain, x2, Transfer, ECG Scale, 10mm/mV, Alarm Settings, Detail Waveform, Pleth

Room	Patient	SpO ₂ %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1100A	Cindi Wallace	100	82 ↓	20	139/99 (107)	Pulse High
1000C	Ben Debone	96	97 ↓	21	138/99 (107)	SpO ₂ High
1600E	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost

Buttons: Map, List, ^V-Waves, Detail, 2:48:31 PM 23-June-1996, Setup, Silence, Help, Print

Buttons: 1000A, 1400A, 1000B, 1400B, 1000C, 1400C, 1000D, 1400D, 1000E, 1500A, 1000F, 1500B, 1100A, 1500C, 1100B, 1500D, 1100C, 1600A, 1100D, 1600B, 1200A, 1600C, 1200B, 1600D, 1200C, 1600E, 1200D, 1600F, 1300A, XFER, 1300B

Figure 9: Patient Setup Screen

Help Screens

The Help Topics Index screen is shown in Figure 10. At any time, if you need help with operating procedures or are seeking information about the *Oxinet II* monitoring system, click the Help function button. The currently displayed screen is replaced with a Help screen showing appropriate help information. You can then click the Index button to select from an index of help topics. The Pg Up and Pg Dn buttons on Help screens select display of preceding or following Help screens. All Help screens also contain the Patient Alarm List.

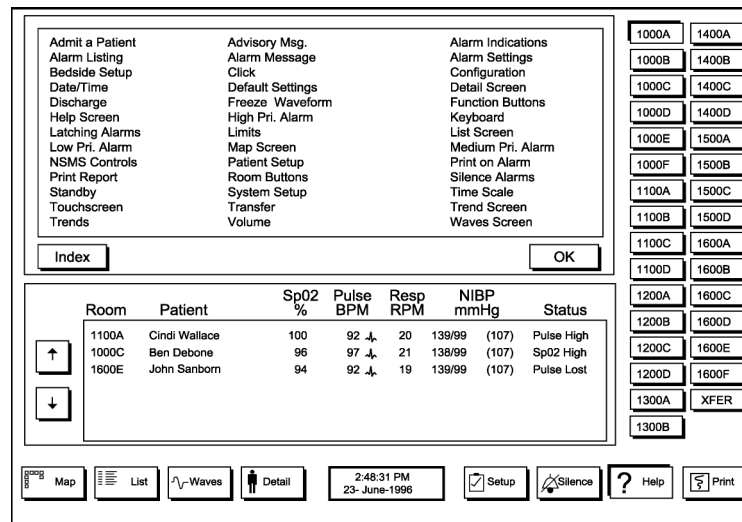


Figure 10: Help Topics Index Screen

DATE/TIME DISPLAY

The date/time display is located in the center of the function buttons on all screens. The date and time and their format are set up or changed by the system administrator.

ALARM INDICATIONS

The central station provides indications of medical and technical alarms. When a monitored patient parameter exceeds a limit set at the bedside station or when a technical condition occurs, an alarm is indicated at the central station. Alarm conditions indicated at the central station are listed in Table 1. Medical and technical alarms are categorized as high, medium, or low priority and each alarm has unique visual and audible characteristics described in the following *Alarm Priority Colors and Flash Rate* and *Alarm Priority Sounds* tables.

Table 1: Central Station Alarm Indications

Alarm	Type/ Priority	Indicated Condition
N-3000 Alarm Indications		
No Pulse	Medical/ High	N-3000 has lost the pulse as measured by the SpO ₂ monitor while no patient motion is detected. Note: If the N-3000 SpO ₂ sensor and N-3100 blood pressure cuff are on the same extremity, when the N-3100 takes a blood pressure measurement, blood flow is temporarily interrupted at the N-3000 sensor and a No Pulse alarm is indicated at the central station.
Asystole	Medical/ High	N-3000 has detected a valid asystole condition.
Pulse Lst	Medical/ Low	N-3000 has lost the pulse while patient motion is detected. Any patient digital data display alternates between dashes and the last known good measurement.
SpO ₂ High	Medical/ Medium	N-3000 measured SpO ₂ above set upper SpO ₂ alarm limit.
SpO ₂ Low	Medical/ Medium	N-3000 measured SpO ₂ below set lower SpO ₂ alarm limit.
Hi Pulse	Medical/ Medium	N-3000 SpO ₂ measured pulse rate above set upper pulse rate alarm limit.
Low Pulse	Medical/ Medium	N-3000 SpO ₂ measured pulse rate below set lower pulse rate alarm limit.
High HR	Medical/ Medium	N-3000 ECG measured heart rate above set upper heart rate alarm limit.

Table 1: Central Station Alarm Indications

Alarm	Type/ Priority	Indicated Condition
Low HR	Medical/ Medium	N-3000 ECG measured heart rate below set lower heart rate alarm limit.
High Resp	Medical/ Medium	N-3000 measured respiration rate above set upper respiration rate alarm limit.
Low Resp	Medical/ Medium	N-3000 measured respiration rate below set lower respiration rate alarm limit.
ECG Noise	Medical/ Medium	Patient motion or other interference has impaired ECG measurements.
Resp Noise	Medical/ Medium	Patient motion or other interference has caused noise that has impaired respiration measurements.
Sensr Dsc	Technical/ Low	The N-3000 SpO ₂ sensor is disconnected.
Ck Sensor	Technical/ Low	The N-3000 SpO ₂ sensor is not functioning properly and should be checked.
Lead Off	Technical/ Low	One or more ECG leads are disconnected.
ECG Cable	Technical/ Low	The ECG cable is disconnected.
Resp Lead	Technical/ Low	One or more ECG leads are disconnected.
Resp Cabl	Technical/ Low	The ECG cable is disconnected.
ECG Fail	Technical/ Low	N-3000 ECG circuitry failure.
Resp Fail	Technical/ Low	N-3000 respiration circuitry failure.

Table 1: Central Station Alarm Indications

Alarm	Type/ Priority	Indicated Condition
N-3100 Alarm Indications		
High Syst	Medical/ Medium	N-3100 measured systolic pressure above set upper systolic pressure alarm limit.
Low Syst	Medical/ Medium	N-3100 measured systolic pressure below set lower systolic pressure alarm limit.
High Dias	Medical/ Medium	N-3100 measured diastolic pressure above set upper diastolic pressure alarm limit.
Low Diast	Medical/ Medium	N-3100 measured diastolic pressure below set lower diastolic pressure alarm limit.
High Mean	Medical/ Medium	N-3100 measured mean pressure above set upper mean pressure alarm limit.
Low Mean	Medical/ Medium	N-3100 measured mean pressure below set lower mean pressure alarm limit.
High PR	Medical/ Medium	N-3100 measured pulse rate above set upper pulse rate alarm limit.
Low PR	Medical/ Medium	N-3100 measured pulse rate below set lower pulse rate alarm limit.
NIBP Err	Technical/ Low	The N-3100 was unable to complete a measurement.
NPB-290 Alarm Indications		
Loss of Pulse	Medical/ High	The NPB-290 cannot find a pulse.
Alarm Limit Violation	Medical/ Medium	The NPB-290 detects a condition that goes beyond an alarm limit setting.

Table 1: Central Station Alarm Indications

Alarm	Type/ Priority	Indicated Condition
Sensor Disconnect	Medical/ Low	The oximetry sensor cable has become disconnected from the NPB-290, or the sensor has become disconnected from the cable, or both have occurred.
NPB-295 Alarm Indications		
Loss of Pulse	Medical/ High	The NPB-295 cannot find a pulse.
Alarm Limit Violation	Medical/ Medium	The NPB-295 detects a condition that goes beyond an alarm limit setting.
Sensor Disconnect	Medical/ Low	The oximetry sensor cable has become disconnected from the NPB-295, or the sensor has become disconnected from the cable, or both have occurred.
N-395/N-595 Alarm Indications		
Loss of Pulse	Medical/ High	The N-395/N-595 cannot find a pulse or detect motion.
Alarm Limit Violation	Medical/ Medium	The N-395/N-595 detects a condition that goes beyond an alarm limit setting.
Sensor Off	Medical/ Low	The sensor has become disconnected from the patient.
Sensor Disconnect	Medical/ Low	The oximetry sensor cable has become disconnected from the N-395/N-595, or the sensor has become disconnected from the cable, or both have occurred.
Communication Alarm Indications		
No Link	Technical/ High	The central station has lost the data communication link with the bedside station.

Alarm Priority Colors and Flash Rate

When an alarm is indicated at the central station, specific colors and flash rates are used to indicate alarm priority for different types and priority levels of alarms on the central station screen as indicated in Table 2.

The colored alarm indications flash at a rate unique to the priority of the alarm. The flashing color becomes a solid color when the alarm is acknowledged. These colors and flash rates are used on the bed buttons, in dots in bed boxes on the Map screen, and in digital data on the Patient List screen, on the Patient Alarm List, and the Patient Detail screen.

Alarms to be latched can also be enabled in system setup. A latched alarm is any alarm at the central station that has not been silenced or acknowledged, and is no longer active. When alarm latching is enabled and the time a condition that causes an alarm is too short to determine the exact nature of the condition, the alarm indication remains as a latched alarm after the condition that caused the alarm no longer exists. Latched alarms can be configured to provide only a visual indication or to provide visual and audible indications.

Table 2: Alarm Priority Colors and Flash Rates

Alarm Priority	Color	Flash Rate
Medical Alarms		
High Priority	Red	Fast
Medium Priority	Yellow	Slow
Low Priority	Yellow	Slow
Technical Alarms		
High Priority	Red	Fast
Low Priority	Yellow	Slow
Latched Alarms		
Any Priority	Blue	Slow

Alarm Priority Sounds

The central station uses different sounds to indicate alarm priority for different types and priority levels of alarms, as indicated in Table 3. Medium and low priority medical alarms can be set at the central station to sound or not sound an audible alarm. See *Using the Patient Setup Screen*.

Table 3: Alarm Priority Sounds

Alarm Priority	Sound
Medical Alarms	
High Priority	High and low pitch tones alternating at a fast rate
Medium Priority	High pitch tone on and off at a fast rate
Low Priority	Low pitch tone on and off at a slow rate
Technical Alarms	
High Priority	High and low pitch tones alternating at a fast rate
Low Priority	Low pitch tone on and off at a slow rate
Latched Alarms	
Any Priority	Low pitch tone on and off at a slow rate

Alarm Silenced Indications

An individual alarm is silenced at the central station using a bed button and the Silence function button, or an alarm is silenced at the central station when it is silenced at the bedside station. The alarm is silenced at the central station for an alarm silence period set in system setup. See *Using Bed Buttons*.

For an individual bed, if one or more patient alarms at the central station have Audible set to OFF, a flashing alarm silence symbol is always displayed on the corresponding bed button and in the message area of the Patient Detail screen for the bed whether or not there is an active alarm at the bedside station. See *Central Station Patient Alarms Settings* in the *Central Station Setup* section.

For an individual bed, if no patient alarms at the central station have Audible set to OFF and an alarm is silenced at the central station or at the bedside station, the alarm silence symbol is displayed and does not flash until the alarm silence period set in system setup has elapsed or the alarm condition at the bedside station ceases.

If an alarm has been silenced, the alarm silence period for that alarm has elapsed, and the *same* alarm condition still exists, the audible alarm sounds again. The bed button begins to flash again with the color associated with the priority of the alarm. If no patient alarms at the central station have Audible set to OFF, the alarm silence symbol also disappears from the bed button when the alarm silence period for that alarm has elapsed.

SYSTEM CONFIGURATION

Introduction
System Configuration

INTRODUCTION

This section describes how to use the System Level screens to change system configurations at the central station for your facility. The paragraphs in the *System Configuration* section can be used individually and in any order. However, a password is required to access the system setup screens. There is no configuration or setup required for the remote transceivers. Refer to the service manuals for the NPB-290, NPB-295, N-395, N-595, or N-3000 and the N-3100 for configuration and setup of those bedside monitors as needed. Patient monitoring continues when you enter the System Level screens, the bed buttons indicate alarm conditions.

SYSTEM CONFIGURATION

Accessing System Setup Screens

To access the System Setup screens and perform System Setup functions, perform the following steps.

- Note: The system continues to monitor any bedside stations already set up while the system set screens are displayed. Alarm indications are displayed on the bed buttons and in the patient alarm list.
- Note: The procedure presented in this paragraph must first be completed before using any system level screen. If the system is returned to a normal operating screen, this procedure will have to be performed again.
- Note: You must have the correct four-digit password to enter the System Level screens.
1. Click the Setup function button. The Patient Setup screen is displayed as shown in Figure 9 on page 26.
 2. Click the System button at the top of the Patient Setup screen. The Passwords screen is displayed as shown in Figure 11 on page 36.

System Configuration

Password: 9999

System Information

1 2 3
4 5 6
7 8 9 ←
0 Enter

OK

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Map List Waves Detail 2:48:31 PM 23-June-1996 Setup Silence ? Help Print

Figure 11: System Setup Password Screen

3. Click the number buttons or use the keyboard to enter the system password and click the Enter button or press the keyboard Enter key. The System Setup Function Select screen is displayed as shown in Figure 12.

Note: The default system password is 9999 for a system shipped from the factory. The system password can be changed. Refer to the paragraph *Setting System Password*.

To exit the System Setup screen, click the OK button on the System Setup Function Select screen. The Passwords screen is displayed. To exit the Password screen, click the OK button.

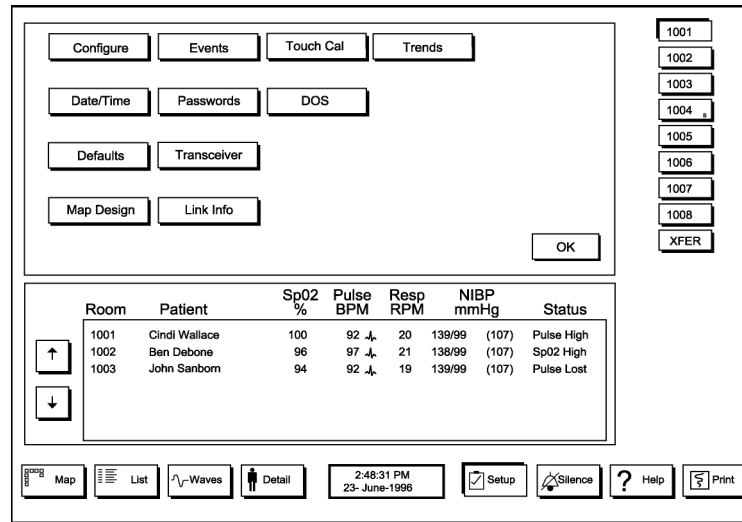


Figure 12: System Setup Function Select Screen

Map Design Screen

When the system is first turned on after receipt from the factory, the Map screen is displayed and is empty. The map is designed to look like the area covered by your *Oxinet II* system on the Map Design screen. To display the Map Design screen, access the System Setup screens and click the Map Design button on the System Setup Selection screen. The Map Design screen is displayed as shown in Figure 13.

Note: Do not monitor patients while modifying the Map Design Screen.

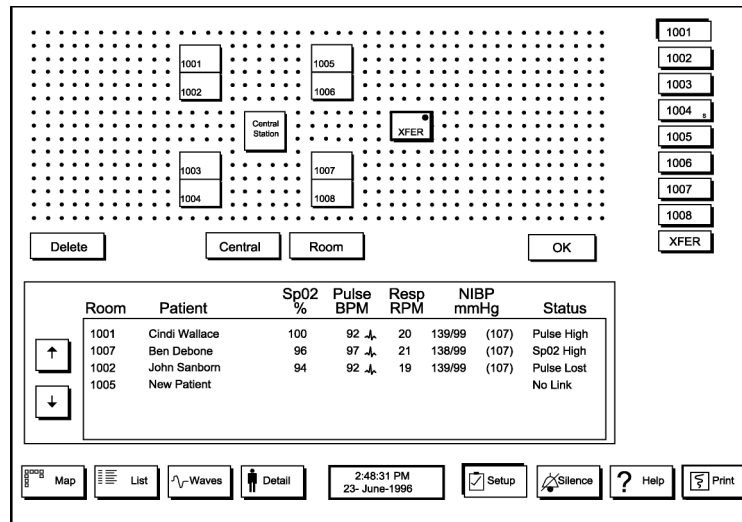


Figure 13: System Map Design Screen

To place or reposition the central station box, click the Central button and then click the map at the location where you want the upper left corner of the central station box.

To place a bed box, click the Room button, then click the map at the location where you want the upper left corner of the bed box. An empty box appears on the map. Click this empty box and the Enter Room ID screen is displayed. Use the attached keyboard, the touchscreen monitor, or the mouse with the on-screen keyboard to enter the bed number for that bed box. When finished, click the Enter key, or press Enter on the attached keyboard.

For radio-link systems, the Enter Transceiver ID screen is displayed. Enter the transceiver ID shown on the label of the bedside station remote transceiver for the bed being set up. Press Enter if the transceiver ID displayed on the Central Station screen is correct. The Map Design screen is again displayed. After you have entered the transceiver ID for the bed, a bed button is displayed with the Room ID number and also in the bed box on the Map Design screen.

For hard-wired systems, the Enter Channel Number screen is displayed. Enter the channel number corresponding to the port on the back of the computer to which the bedside station is connected. Click the Enter button. The Map Design screen is again displayed. After entering the channel number for a bed, a bed button is displayed on the right side of the screen with the Room ID number. The Room ID number is also displayed in the bed box on the Map Design screen.

Note: As bed boxes are added to the Map Design screen, corresponding bed buttons appear and are arranged in ACSII ascending order with any existing bed buttons. For example, a bed button with the number 10 appears in order between a bed button with the number 1 and a bed button with the number 2.

Note: For a room containing more than one monitored bed, another bed box has to be placed on the map for each additional bed in the room.

To delete a bed box or to delete the central station box from the Map screen, click the Delete button, then click the bed box or the central station box to be deleted.

Note: A room that has a patient assigned to it cannot be deleted.

Note: To move a room on the Map screen to a new location, the room must first be deleted and then placed again.

When you are finished with changes to the map, click the OK button on the Map Design screen.

Setting System Passwords

To display the Passwords Maintenance screen, access the System Setup screen and click the Passwords button on the System Setup selection screen. The Passwords Maintenance screen is displayed as shown in Figure 14.

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Figure 14: System Passwords Maintenance Screen

To assign a new password, click the New button. An on-screen keypad appears. Enter a four-digit password and click the Enter button when finished or use an attached keyboard to enter the password and press Enter.

Note: If password “9999” is not deleted, you will still be able to use both password “9999” and the new password. If you wish to use only the new password, then you must delete password “9999”.

To delete a password, click the up arrow, down arrow, Pg Up, or Pg Dn buttons as needed to highlight the password to be deleted. Click the Delete button.

When finished setting system passwords, click the OK button.

Setting System Date and Time

To set or change the system display format, date, or time, access the System Setup screen and click the Date/Time button on the System Setup Function Select screen. The System Date/Time Setup screen is displayed as shown in Figure 15.

Note: When you click and hold the up arrow or down arrow button or continuously touch the up arrow or down arrow button, its function is repeated rapidly.

System Configuration

System Date/Time Setup

Month: ↑ 6 ↓

Day: ↑ 23 ↓

Year: ↑ 95 ↓

Hour: ↑ 2 ↓

Minute: ↑ 48 ↓

AM/PM PM

Formats

Date: dd-mmm-yyyy

Time: hh:mm:ss

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

2:48:31 PM
23-June-1996

☒ Setup
☐ Silence

Figure 15: System Date/Time Setup Screen

To set or change the system date, click the up arrow or down arrow button adjacent to Month, Day, or Year.

Note: The last two digits of the year can be displayed only for the years 1980 through 2079.

To set or change the date display format, click the Date button to cycle through the display formats.

To set or change the time display format, click the Time button to cycle through the display formats.

To set or change the system time, click the up arrow or down arrow button adjacent to Hour or Minute. Click the AM/PM button to toggle the display between AM and PM.

Note: The AM/PM button is only displayed when a 12-hour clock format is selected.

After you have set or changed the system display format, date, or time, click the OK button.

Setting Up System Configuration

To set or change the system configuration, access the System Setup screen and click the Configure button on the System Setup selection screen. The System Configuration screen is displayed as shown in Figure 16. When finished setting or changing system configurations, click the OK button.

The System Configuration screen includes the following elements:

- System Configuration Section:**
 - Volume
 - Freeze (ON)
 - Silence (3 min)
 - Latch (Vis./Audio)
 - OK button
- Patient Data Table:**

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link
- Navigation and Status Bar:**
 - Buttons: Map, List, Waves, Detail, Setup, Silence, Help, Print
 - Status: 2:48:31 PM, 23-June-1996
- Room Selection List (Right):** 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, XFER

Figure 16: System Configuration Setup Screen

Setting Waveform Freeze

To set the system to freeze plethysmograph and ECG waveforms when the waveform is clicked, click the Freeze button as needed until ON is displayed to the right of the button. If waveform freeze is not desired, click the Freeze button as needed until OFF is displayed to the right of the button.

Setting System Alarm Silence Period

To set or change the alarm silence period for the central station for monitored bedside station alarms, click the Silence button on the System Configuration screen as needed until the desired alarm silence period is displayed to the right of the button. The alarm silence period can be set for a duration from 30 seconds to 4 minutes, in 30-second increments.

Note: The setting of the alarm silence period at the central station has no effect on the alarm silence period at any bedside station.

Setting System Alarm Latching

To set the system alarm latching configuration for the central station, click the Latch button. To set the central for no alarm latching, click the Latch button as needed to display OFF in the window to the right of the Latch button. To latch only visual alarms, click the Latch button as needed to display Visual. To latch both visual and audible alarms, click the Latch button as needed to display Vis./Audio.

Note: The setting of alarm latching at the central station has no effect on alarm latching at any bedside station.

Setting System Volume Levels

To set the central station alarm volume levels or the volume of the “click” sound when the screen is touched, click the Volume button. The System Volume Setup screen is displayed as shown in Figure 17.

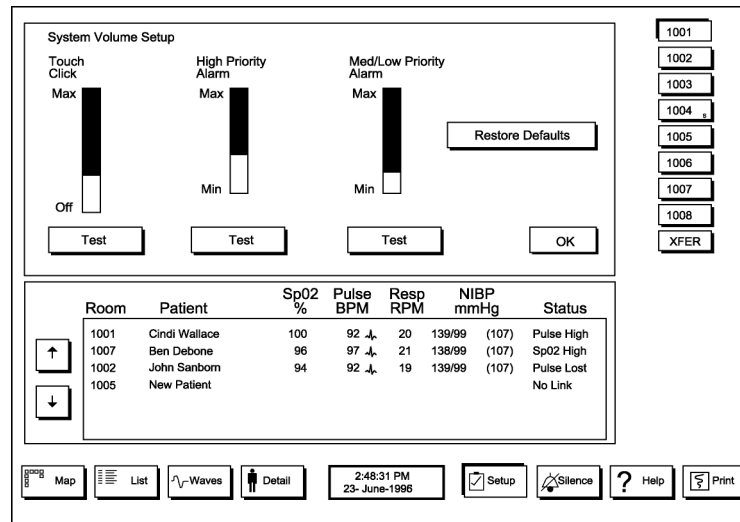


Figure 17: System Volume Setup Screen

Click inside the volume setting slider and drag the level indicator to obtain the desired volume level. When the mouse button is released or when you lift your finger from the touchscreen monitor, an example of the click or alarm is heard at the set volume level.

Note: If you adjust a slider bar level and move the pointer outside of the slider bar before the mouse button is released or if, with a touchscreen monitor, you move your finger outside of the slider bar and you lift your finger, the slider bar indicates a new adjusted level. However, the example of the click or alarm is not heard and the actual volume level is not adjusted.

To restore factory default volume levels, click the Restore Defaults button.

Click the Test button under a volume setting slider bar to hear an example of the click or alarm at the actual set volume level. Click the OK button after you have set system volume levels.

Setting System Defaults Settings

To set or change system defaults settings, access the System Setup screen and click the Defaults button. The System Defaults Setting screen is displayed as shown in Figure 18.

The screenshot shows the 'System Default Settings' window. It contains several settings buttons: 'Alarm Settings', 'Standby' (set to OFF), 'SpO₂ Gain' (set to x1), 'ECG Scale' (set to 10mm/mV), and 'Default Waveform' (set to Pleth). There is an 'OK' button at the bottom right of the settings area. To the right of the settings area is a vertical list of room numbers: 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, and XFER. Below the settings area is a table with patient information.

Room	Patient	SpO ₂ %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO ₂ High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

At the bottom of the screen is a navigation bar with buttons: Map, List, Waves, Detail, a date/time display (2:48:31 PM, 23-June-1996), Setup, Silence, Help, and Print.

Figure 18: System Defaults Setup Screen

After you have set the system defaults, click the OK button on the System Defaults Setting screen.

Setting System Default Channel Standby Setting

To set the system default Standby setting, click the Standby button as needed to display ON or OFF. When Standby is set to ON, whenever the discharge function is performed or a new bed box is added to the Map Design screen, the bed is set to standby-ON. When Standby is set to OFF, whenever the discharge function is performed or a new bed box is added to the Map Design screen, the bed is set to standby-OFF.

Setting System Default Channel SpO2 Gain

To set the default SpO2 gain, click the SpO2 Gain button as needed to cycle through gain settings of x0.5, x1, x2, x3, or x4. The value set will be set initially whenever the discharge function is performed or a new bed box is added to the Map Design screen.

Setting System Default ECG Scale

To set the default ECG scale, click the ECG Scale button as needed to cycle through gain settings of 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, and 40 mm/mV. The value set will be set initially whenever the discharge function is performed or a new bed box is added to the Map Design screen.

Setting System Default Display Waveform

To set the default waveform that is displayed initially on the Patient Detail screen, press the Default Waveform button to select either ECG (N-3000 only) or Pleth (plethysmograph). The waveform selected will be the waveform displayed initially on the Patient Detail screen whenever the discharge function is performed or a new bed box is added to the Map Design screen.

Setting System Default Channel Alarms Setting

To set system default alarm settings, click the Alarm Settings button. The System Default Channel Alarm Settings screen is displayed as shown in Figure 19.

System Configuration

System Default Settings

Alarm	Print	Strip	Audible
No Pulse	OFF	OFF	ON
Pulse Lost	OFF	OFF	ON
SpO ₂ High	OFF	STRIP	ON
SpO ₂ Low	OFF	OFF	ON
Pulse High	OFF	OFF	ON
Pulse Low	OFF	LASER	ON
Syst. High	OFF	OFF	ON
Syst. Low	OFF	OFF	ON
Diast. High	OFF	OFF	ON
Diast. Low	OFF	OFF	ON

Pg Up

↑

↓

Pg Dn

Print

Strip

Audible

Off

Off

On

Restore Defaults

OK

Room	Patient	SpO ₂ %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1100A	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1000C	Ben Debone	96	97 ↓	21	138/99 (107)	SpO ₂ High
1600E	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost

1000A 1400A

1000B 1400B

1000C 1400C

1000D 1400D

1000E 1500A

1000F 1500B

1100A 1500C

1100B 1500D

1100C 1600A

1100D 1600B

1200A 1600C

1200B 1600D

1200C 1600E

1200D 1600F

1300A XFER

1300B

Map

List

Waves

Detail

2:48:31 PM

23-June-1996

Setup

Silence

Help

Print

Figure 19: System Default Channel Alarm Settings Screen

Click the up arrow, down arrow, Pg Up, or Pg Dn button to scroll the list of alarms and highlight the alarm for which defaults are to be set or changed.

Alarm defaults are the settings that will be in effect when a new patient is admitted or a new bed box is added to the Map Design screen.

Click the Print, Strip or Audible button as needed to set the alarm defaults for the highlighted alarm. With Print set to ON, the central station automatically prints a patient data report on an attached (optional) laser printer whenever the selected alarm is received from the bedside station. With Print set to OFF, a patient data report is not printed.

With Strip set to STRIP, a patient waveform printout automatically prints on the (optional) internal thermal printer at the central station when the selected alarm is received. When Strip is set to LASER, a patient waveform is printed on the attached laser printer. When Strip is set to OFF, no patient waveforms are automatically printed.

When Audible is set to ON, the central station to generate an audible alarm sound when the selected alarm is received. When Audible is set to OFF, no alarm sounds at the central station when the selected alarm is received.

To restore system default alarm settings to the factory default settings, click the Restore Defaults button. After you set the system defaults for alarms, click the OK button.

Displaying Radio-Link System Channel Setups

To display radio-link channel settings in radio-link systems only, access the System Setup screens and click the Link Info button. The Link Information screen is displayed as shown in Figure 20.

The screen is titled 'Link Information' and contains the following elements:

- Room Information Table:**

Room	Remote ID	Bedside ID
1001	512072	80100415
1002	523663	803003AC
1003	510966	8011431D
1004	536228	
1005	557003	80084278
1006	512083	8039704C
1007	557017	801147DB
1008	501994	802010C0
- Navigation Buttons:** Pg Up, ↑, ↓, Pg Dn, OK.
- Patient List Table:**

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link
- Bottom Bar:** Map, List, Waves, Detail, 2:48:31 PM 23-June-1996, Setup, Silence, Help, Print.

Figure 20: Radio-Link System Link Information Screen

Click the up arrow, down arrow, Pg Up, or Pg Dn button to view a list of the room (bed) numbers, remote IDs, and bedside IDs active in your system. Click the OK button after you have viewed system channel setups.

Radio-Link Transceiver Maintenance

Transceiver maintenance must be performed when no patients are being monitored. To perform system transceiver setup and maintenance in radio-link systems only, access the System Setup screens and click the Transceiver button. The Transceiver Maintenance screen is displayed as shown in Figure 21. Click the OK button when finished with transceiver setup.

Transceiver Maintenance

Central 1

Central 2

Central 3

Master/Slave Master

Central ID 39

Program

Deassign

1001

1002

1003

1004

1005

1006

1007

1008

XFER

OK

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Map

List

Waves

Detail

2:48:31 PM

23-June-1996

Setup

Silence

Help

Print

Figure 21: System Transceiver Maintenance Screen

Click the Master/Slave button to change the display to the right of the button and designate the central transceiver as a master or slave. For spread spectrum systems, the setting will always be master. Exactly one central transceiver must be set to master. A *slave* central transceiver is synchronized to a *master* central transceiver.

Note: Plug the end of the synchronization cable labeled “master” into the central transceiver that has been designated as master.

Click the Central ID button to select a number from 1 to 53 for the transceiver central ID. For spread spectrum systems, the setting will always be 1. If more than one Central transceiver is being used on a fixed frequency system, select ID numbers that are separated by at least four digits. After changing a radio system Central ID, the Central Station must be turned off for 2 minutes prior to resuming normal monitoring. Once communication is established between a remote bedside transceiver and the central station, the remote transceiver looks for the central station transceiver monitor IDs entered on this screen.

Note: Do not change the Master/Slave setting or Central ID without first contacting Nellcor’s Technical Service Department or Customer Support Engineering.

Note: To avoid radio interference when making Central ID choices, consider other radio systems in or near the facility, operating in the 902 to 928 MHz range.

The Central ID on this page must be changed when patients are not being monitored. The remote transceiver will identify this change and reestablish the communication link with the central station and ignore another central station with a different Central ID that was programmed with other remote transceiver IDs. The Central ID differs from the remote transceiver ID in that each remote transceiver has a fixed and unique ID number that is used in the communication protocol. Each remote transceiver ID has to be programmed into the central stations. (See *Programming a Transceiver ID*.)

Programming a Transceiver ID

Click the Program button to set the remote ID for any one or all remote transceivers in the system. The programming screen is displayed, as shown in Figure 22.

The screenshot shows a software interface for transceiver maintenance. At the top, a dialog box titled "Transceiver Maintenance" prompts the user to "Select room and the remote to program." It contains fields for "Room" (set to 1001) and "Remote ID" (set to 512073), with "OK" and "Cancel" buttons. To the right of the dialog is a vertical list of room numbers from 1001 to 1008, plus an "XFER" button. Below the dialog is a table with patient data. The table has columns for Room, Patient, SpO2 %, Pulse BPM, Resp RPM, NIBP mmHg, and Status. The data rows are as follows:

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

At the bottom of the screen is a toolbar with icons for Map, List, Waves, Detail, a status bar showing "2:48:31 PM 23-June-1996", and buttons for Setup, Silence, Help, and Print.

Figure 22: Transceiver Programming Screen

Note: If an ID number is entered that has already been selected, the cursor moves to the left of the entry line giving no way to delete the bad entry. If this happens, enter a valid transceiver number that is not in use, or enter any six-digit

number and use the backspace key to delete the number. A third option is to select any function key at the bottom of the screen except setup, enter the function, exit, then re-enter the setup screen. Click the Room button as needed to cycle through all available bed numbers and select the bed you wish to change or set the transmitter ID. Click the Remote ID button and a keypad is displayed. Click the numbers to enter the remote ID. Click the OK button in the pop-up window when finished.

Deassigning a Transceiver ID

To deassign a remote ID from a bed, click the Deassign button on the System Transceiver Maintenance screen. The Deassign screen is displayed as shown in Figure 23.

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Figure 23: Transceiver Deassign Screen

Click the Room button as needed to cycle through all available bed numbers and select the bed for which you wish to deassign the remote ID. Click the OK button in the pop-up window to complete the deassignment. Click the Cancel button to quit the deassignment and make no changes.

Displaying Channel Setups in Hard-Wired Systems

To display channel assignments in hard-wired systems only, access the System Setup screens and click the Link Info button. The Link Information screen is displayed, as shown in Figure 24.

Note: This screen is for information only. No changes can be made.

The screenshot displays the 'Link Information' screen. It features a table for room/channel assignments, a list of room buttons on the right, and a table for patient vital signs at the bottom.

Room	Channel	Bedside ID
1001	1	80100415
1002	2	803003AC
1003	3	8011431D
1004	4	
1005	5	80084278
1006	6	8039704C
1007	7	801147DB
1008	8	802010C0

Navigation buttons: Pg Up, ↑, ↓, Pg Dn, OK.

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97	21	138/99 (107)	SpO2 High
1008	John Sanborn	94	92	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Room buttons: 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, XFER.

Bottom bar: Map, List, Waves, Detail, 2:48:31 PM 23-June-1998, Setup, Silence, Help, Print.

Figure 24: Hard-Wired System Link Information Screen

Performing Touchscreen Calibration

To perform a touchscreen monitor calibration, access the System Setup screen and click the Touch Cal button. Observe the screen and touch it where indicated to calibrate the touchscreen monitor. A touchscreen calibration should be performed every time the computer or touchscreen monitor has been turned off and back on again, or when necessary.

Note: The Touch Cal button will not show on the screen until the touchscreen has been touched. Before attempting to calibrate the touchscreen use the touchscreen function.

Exiting to DOS

WARNING: Patient safety could be compromised if the Exit-to-DOS function is used while patients are being monitored. While patient monitoring continues at the bedside stations, the Exit-to-DOS function stops all display of bedside station status and alarms at the central station. The DOS function should be used only by the system administrator or other qualified personnel and when patient safety will not be compromised.

To exit to DOS from the *Oxinet* II system software, access the System Setup screen and click the DOS button on the System Setup Selection screen. You are prompted to confirm that you want to exit to DOS. Click the Yes button to exit to DOS. Click the No button to return to the System Setup Selection screen.

To restart the *Oxinet* II system from DOS, change the directory to the NSMS directory and enter START at the DOS prompt.

Setting System Trends

To set or change time intervals for system trends that are used for patient data printouts on an attached laser printer, access the System Setup screens and click the Trends button on the System Setup Selection screen. The System Trends Setup screen is displayed as shown in Figure 25.

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Figure 25: System Trends Setup Screen

To set the time interval to be used for a summary patient data printout, click the Summary button to cycle through the values and select the desired time interval. Available selections are 15 or 30 minutes, or 1, 2, 4, 8, 12, or 24 hours.

To set the time interval to be used for an alarm patient data printout, click the Alarm button to cycle through the values and select the desired time interval. Available selections are 15 or 30 minutes, or 1, 2, 4, 8, 12, or 24 hours.

After you have set time intervals for the system printouts, click the OK button. The displayed values are set as the system trend values.

Displaying a List of System Events

The central station computer maintains a log of system events such as when the computer is turned on or when System Setup has been accessed. To display a list of up to 99 system events, access the System Setup screens and click the Events button on the System Setup selection screen. The System Events screen is displayed as shown in Figure 26.

System Configuration

Events

4 Events

Pg Up

↑

↑

Pg Up

01

2-Feb

3:15PM

00100

09999

System setup.

02

2-Feb

3:13PM

00200

00000

System boot.

03

1-Feb

4:16PM

00100

09999

System setup.

04

1-Feb

2:49PM

00100

09999

System setup.

Erase

Print

OK

1001

1002

1003

1004

1005

1006

1007

1008

XFER

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1001	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1007	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1002	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost
1005	New Patient					No Link

Map

List

Waves

Detail

2:48:31 PM
23-June-1998

Setup

Silence

Help

Print

Figure 26: System Events Screen

Click the up arrow, down arrow, Pg Up, or Pg Dn buttons to scroll a list of a maximum of 99 of the most recent system events.

To erase the list of system events from the computer memory, click the Erase button. You are prompted to confirm that you do want to erase the entire list of system events. Click the Yes button to erase the list. Click the No button to leave the list intact.

To print the current list of system events on the facility-provided laser printer connected to the central station computer, click the Print button next to the Erase button on the System Events screen.

Note: Do not click the Print function button at the bottom right side of the central station screen to print a list of system events. The Print function button is described in *Controls, Indicators, and Screens*.

After you have displayed the list of system events, click the OK button.

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BEDSIDE STATION SETUP

Introduction
Bedside Station Setup Overview
Bedside Station Communication Connections
NPB-290 Setup
NPB-295 Setup
N-395 Setup
N-595 Setup
N-3000 Setup
N-3100 Setup
N-3200 Setup

INTRODUCTION

Each bedside station must be set up for use with the *Oxinet II* system. This setup should be performed by a qualified technician.

BEDSIDE STATION SETUP OVERVIEW

The communication link between the NPB-290, NPB-295, N-395, N-595, and N-3000 in the bedside station and the central station must be established. The NPB-290, NPB-295, N-395, N-595, N-3000 (and the N-3100 and the N-3200, if they are part of the bedside station) must be set up for patient monitoring.

BEDSIDE STATION COMMUNICATION CONNECTIONS

There are two methods for connecting the bedside station for communication depending on whether the *Oxinet II* system is a radio-link system or a hard-wired system.

Radio-Link Systems

Radio-links can be established between the *Oxinet II* system and NPB-290, NPB-295, N-395, N-595, and N-3000 monitors. The following paragraphs describe setup of the:

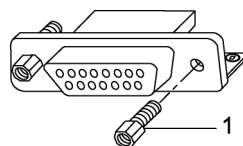
- NPB-290, NPB-295, N-395, and N-595 Radio-Link
- N-3000 Radio-Link

Bedside Station Setup

NPB-290, NPB-295, N-395, and N-595 Radio-Link

The NPB-290, NPB-295, N-395, and N-595 must be modified to operate with the *Oxinet II* system. The data port connector on the NPB-290, NPB-295, N-395, and N-595 must have hex standoffs installed.

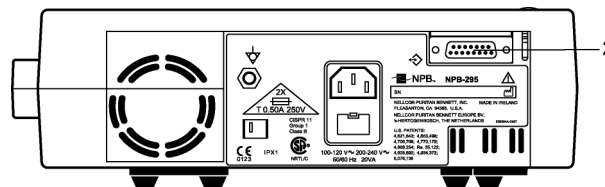
1. Install two hex standoffs (Figure 27, item 1) on NPB-290, NPB-295, N-395, or N-595 data port connector (Figure 28, item 2). Refer to NPB-290, NPB-295, N-395, or N-595 service manual for unit disassembly.



1. Hex Standoff

Figure 27: Hex Standoff Installation

2. Connect *Oxinet II* radio cable 15-pin connector to pulse oximeter data port connector (Figure 28, item 2).



2. Data Port Connector

Figure 28: Data Port

3. Connect *Oxinet II* radio cable 6-pin connector (Figure 29, item 3) to radio 6-pin connector (item 4).

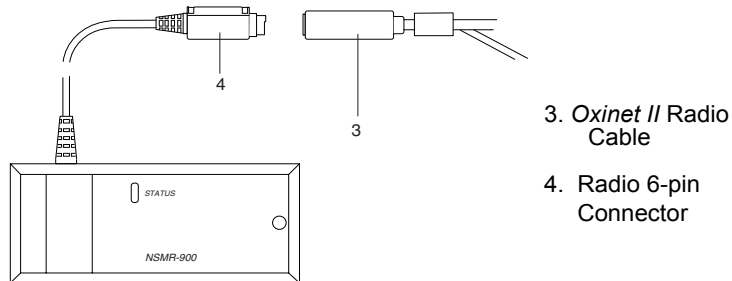


Figure 29: Radio Cable Connection

4. Connect *Oxinet II* radio cable pig-tail connector (Figure 30, item 5) to radio power supply DC output cable (item 6).

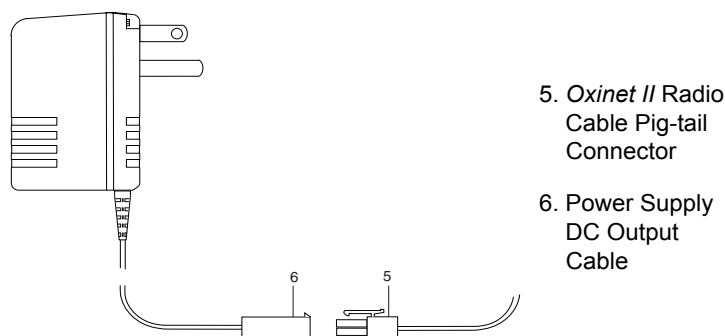


Figure 30: Radio Power Connection

Note: The NPB-290, NPB-295, N-395, and N-595 and the radio must be powered by AC power to transmit signals to the *Oxinet II* system.

5. Connect radio power supply to AC outlet.
6. Communication must be set for EIA-232 at a baud rate of 2400 for central systems set to SpO₂ only. All other systems must be set to a baud rate of 9600. Refer to the NPB-290, NPB-295, N-395, or N-595 service

manual for directions for setting up the NPB-290, NPB-295, N-395, or N-595 communication features.

7. Refer to applicable operator's manual for complete instructions for use, including warnings, cautions, and specifications, of the pulse oximeter and *Oxinet II* monitoring system.

N-3000 Radio-Link

Note: The N-3000 (N-3100, N-3200) and the radio must be powered by AC power to transmit signals to the *Oxinet II* system.

1. Remove the adhesive backing from the quick-lock strips on the remote radio, position the radio with its cable hanging over the rear of the N-3000, and press the radio down onto the top of the N-3000.
2. Make sure the N-3000 is off and then connect the cable attached to the remote transceiver to the serial port connector on the rear panel of the N-3000 as shown in Figure 31. The N-3000 must be configured for 3.3 Vdc power on pin 6 of the serial port connector. Communication must be set for EIA-232 at a baud rate of 2400 for central systems set to SpO₂ only. All other systems must be set to a baud rate of 9600. Refer to the N-3000 service manual for directions for setting up the N-3000 communication features.

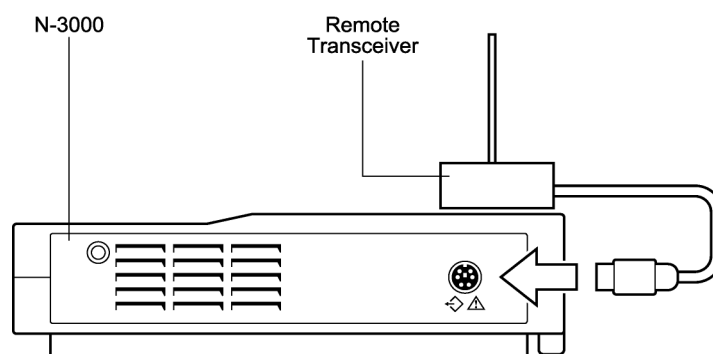


Figure 31: Bedside Station Radio-Link Connection

Hard-Wired Systems

Note: The NPB-290, NPB-295, N-395, N-595, and N-3000 and the radio must be powered by AC power when connected to the *Oxinet II* system.

Hard-Wired links can be established between the *Oxinet II* system and NPB-290, NPB-295, N-395, N-595, and N-3000 monitors. The following paragraphs describe setup of the:

- NPB-290, NPB-295, N-395, and N-595 Hard-Wired Link
- N-3000 Hard-Wired Link

NPB-290, NPB-295, N-395 and N-595 Hard-Wired Link

The NPB-290, NPB-295, N-395, and N-595 must be modified to operate with the *Oxinet II* system. The data port connector on the NPB-290, NPB-295, N-395, and N-595 must have hex standoffs installed.

1. Install two hex standoffs (Figure 32, item 1) on oximeter data port connector (Figure 33, item 2). Refer to oximeter service manual for oximeter disassembly.

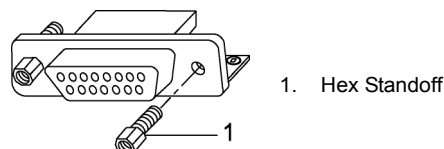


Figure 32: Hex Standoff Installation

2. Connect the *Oxinet II* hard-wire cable 15-pin connector to the pulse oximeter data port connector (Figure 33, item 2).

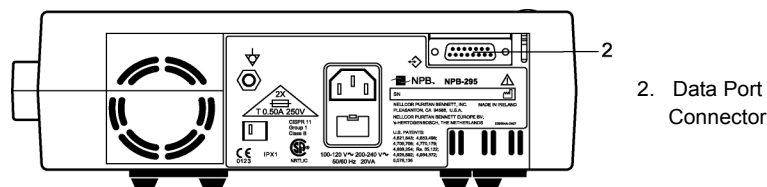


Figure 33: Data Port

3. Connect *Oxinet II* hard-wire cable 8-pin connector (Figure 34, item 3) to *Oxinet II* wall outlet (item 4).

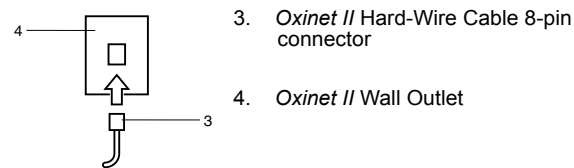


Figure 34: Oxinet II Wall Outlet

4. Communication must be set for EIA-422 to match protocol set at the central station at a baud rate of 9600. Refer to the NPB-290, NPB-295, N-395, or N-595 service manual for setting up the communication features.
5. Refer to the applicable operator's manual for complete instructions for use, including warnings, cautions, and specifications, of the pulse oximeter and the *Oxinet II* monitoring system.

N-3000 Hard-Wire Link

Connect the cable from the wall connector to the serial port connector on the rear panel of the N-3000 as shown in Figure 35. Communication must be set for EIA-422 to match the protocol set at the central station at a baud rate of 9600. Refer to the N-3000 service manual for directions for setting up the N-3000 communication features.

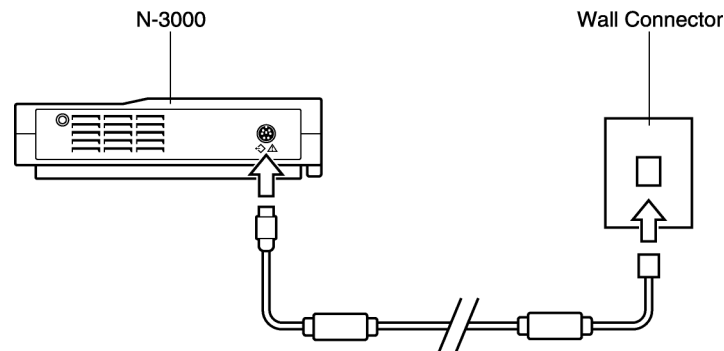


Figure 35: Bedside Station Hard-Wired Connection

NPB-290, NPB-295, N-395, OR N-595 SETUP

Refer to the NPB-290, NPB-295, N-395, or N-595 operator's manual for detailed instructions for setting up the monitor for patient monitoring, connecting it to a patient, and setting alarm limits. NPB-290, NPB-295, N-395, or N-595 alarm limits must be set or verified for each patient monitoring situation.

N-3000 SETUP

Refer to the N-3000 operator's manual for detailed instructions for setting up the monitor for patient monitoring, connecting it to a patient, and setting alarm limits. N-3000 alarm limits must be set or verified for each patient monitoring situation.

An SPS external power supply, a PSS-1 power slice or an N-3200 display/printer must be connected to the stack for the N-3000 serial port connector to be active. Refer to the operator's manual for each of these monitors for stacking instructions.

N-3100 SETUP

Refer to the N-3100 operator's manual for detailed instructions for stacking the N-3100 with the N-3000 and N-3200, setting up the monitor for patient monitoring, connecting it to a patient, and setting alarm limits. N-3100 alarm limits must be set or verified for each patient admission.

Verify that the N-3100 stacked with the N-3000 are both in the correct operating mode—adult-pediatric or neonatal—as appropriate for the patient being monitored.

An SPS external power supply, a PSS-1 power slice or an N-3200 display/printer must be connected to the stack for the N-3000 serial port connector to be active.

N-3200 SETUP

Refer to the N-3200 operator's manual for detailed instructions for stacking the N-3000 and N-3100 and setting up the display/printer for use.

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CENTRAL STATION HOOKUP

- General Information
- Power Requirements
- Central Station Site Selection
- Central Station Antenna Location (Radio-Link Only)
- Hardware Hookup
- System Interconnect (Radio-Link)
- System Interconnect (Hard-Wired)
- Monitor Setup

GENERAL INFORMATION

Before moving or installing your *Oxinet II* monitoring system, contact Nellcor's Technical Services Department or your local Nellcor representative.

This section provides general information on reconnecting your *Oxinet II* system after installation and after moving it.

Before moving a bedside station in a radio-link system, contact Nellcor's Technical Services Department or your local Nellcor representative to determine the optimum location for the bedside station. Refer to the operator's and service manuals for the individual monitor being moved.

POWER REQUIREMENTS

Oxinet II system power cords should be connected only to an approved, grounded outlet capable of providing power for the *Oxinet II* system as indicated in the *Specifications* section. This outlet should be close enough to the location of the central station that only the power cord supplied with the uninterruptible power supply (UPS) is used and a power extension cord is not used.

Caution: For USA locations, do not connect any components of the *Oxinet II* system to an electrical outlet controlled by a wall switch.

CENTRAL STATION SITE SELECTION

When considering a new location for the central station, find a location that is accessible to the operator and where the monitor is in full view of all who will be looking at it. In addition to accessibility, you will need adequate counter space for all components of the central station that are used. Table 4 lists the space used by each of the components of the central station.

Table 4: Central Station Component Space Requirements

Central Station Component	Counter Space Requirement
Computer	22.8 cm (9 in.) x 38.1 cm (15 in.) x 43.2 cm (17 in.) tall
19-inch Touchscreen Monitor	Depends on the monitor supplied with your system. Monitors are purchased from different manufacturers.
15-inch Touchscreen Monitor	Depends on the monitor supplied with your system. Monitors are purchased from different manufacturers.
Uninterruptible Power Supply	33.0 cm (13.1 in) x 8.6 cm (3.4 in.)
Keyboard	47 cm (18.5 in.) x 20.3 cm (8.0 in.)
Mouse (Typical mouse pad)	(9.25 in.) x 20.3 cm (8 in.)

In addition to adequate counter space, adequate ventilation space must be provided around the central station computer, monitor, and uninterruptible power supply. There should be a minimum of 1.5 inches from the top, front, sides, and back of these central station components to any wall or other enclosing surface.

It is also recommended that a minimum of 4 inches of space from the back of the computer be available for cables. There must also be a minimum of 4 inches of space in front of the computer to accommodate changing thermal printer paper.

Caution: Do not put the computer, touchscreen monitor, or uninterruptible power supply inside a cabinet or other closed space where air cannot freely flow around these components.

LOCATION OF CENTRAL STATION ANTENNA (RADIO-LINK ONLY)

The locations of the central station antenna must be determined by Nellcor's Technical Service Department. The antennas must be a minimum of 6 feet from the floor with their ground plates in the same horizontal plane. It is recommended that the antennas be attached to the ceiling with the antenna elements pointing down.

Refer to the site survey conducted for your facility and to your Customer Installation Packet for suggested optimum location for the central station antennas.

HARDWARE HOOKUP

Hardware hookup consists of placing the central station at the selected location and placing components for each of the bedside stations. This is followed by connecting the necessary cables and components as described in the paragraph titled *System Interconnect*, page 68, to make the system operate properly. Once the system is hooked up, proper operation of the system can be verified by performing the procedures in the *Performance Verification* section of the *Oxinet II* system service manual.

Central Station Hardware Installation

Place the computer and touchscreen monitor at the location selected for the central station. The UPS can be placed in the same area as the computer and monitor or further away such that the supplied power cords can be connected between the computer and monitor and the UPS.

The keyboard and mouse are optional for operating the *Oxinet II* system. These components are used at the central station location. The exact placement of central station components is determined by the needs of the facility. Set up the central station as described in the *Central Station Setup* section.

Bedside Station Hardware Installation

Set up each bedside station as described in the *Bedside Station Setup* section.

SYSTEM INTERCONNECT (RADIO-LINK)

This section describes how to hook up the central station in a radio-link system.

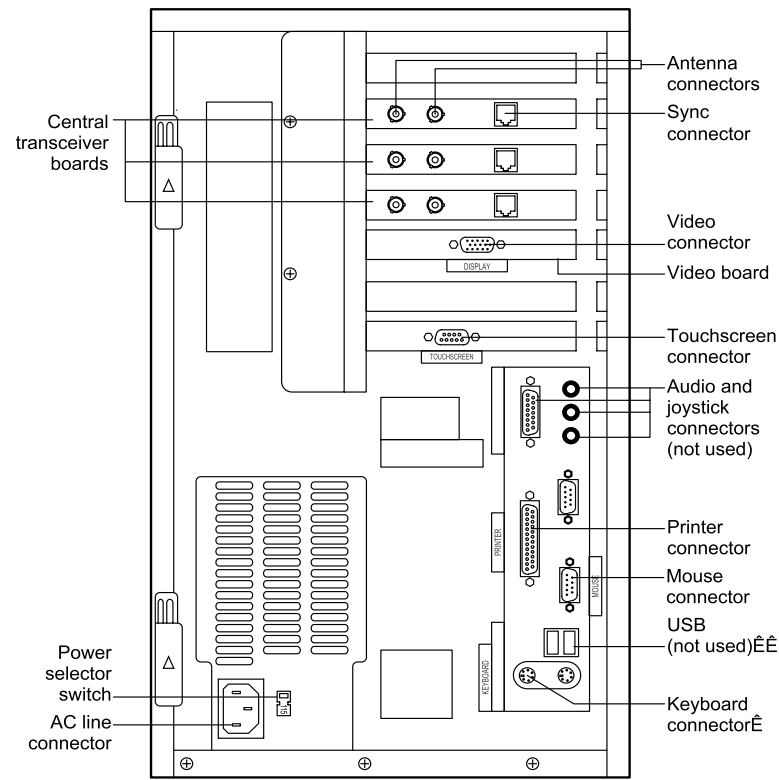


Figure 36: Computer Rear Panel Connectors (Radio-Link)

Refer to Figure 36. Connect central station components using the following procedure.

1. Verify that the power selector switch is set to your facility's wall plug voltage.
2. If a mouse is used in the installation, connect the mouse to the connector marked "MOUSE" at the back of the computer.

3. If a keyboard is used in your installation, connect the keyboard to the connector marked “KEYBOARD” at the back of the computer.
4. If your touchscreen monitor does not have the video cable permanently attached to the monitor, connect the end marked “MONITOR” to the monitor video connector.
5. Connect the other end of the video cable to the video drive connector marked “DISPLAY” at the back of the computer.
6. Connect the end of the touchscreen control cable marked “TO INTELLITOUCH SCREEN” to the 9-pin connector on the back of the monitor.
7. Connect the other end of the touchscreen control cable marked “TO INTELLITOUCH CONTROLLER” to the touchscreen connector marked “TOUCHSCREEN” at the back of the computer.
8. Connect antenna cables to the connectors marked “ANT. A” and “ANT. B” on the computer.

SYSTEM INTERCONNECT (HARD-WIRED)

This section describes how to hook up the central station in a hard-wired system.

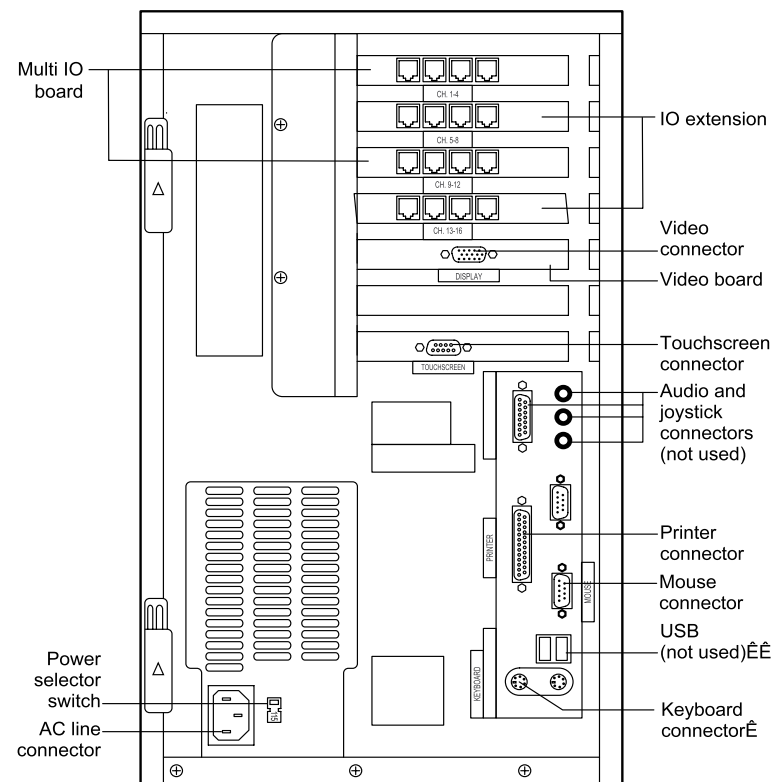


Figure 37: Computer Rear Panel Connectors (Hard-Wired)

Refer to Figure 37. Connect central station components using the following procedure.

1. Verify that the power selector switch is set to your facility's wall plug voltage.
2. If a mouse is used in the installation, connect the mouse to the connector marked "MOUSE" at the back of the computer.

3. If a keyboard is used in your installation, connect the keyboard to the marked “KEYBOARD” at the back of the computer.
4. If your touchscreen monitor does not have the video cable permanently attached to the monitor, connect the end marked “MONITOR” to the monitor video connector.
5. Connect the other end of the video cable to the video drive connector marked “DISPLAY” at the back of the computer.
6. Connect the end of the touchscreen control cable marked “TO INTELLITOUCH SCREEN” to the 9-pin connector on the back of the monitor.
7. Connect the other end of the touchscreen control cable marked “TO INTELLITOUCH CONTROLLER” to the touchscreen connector marked “TOUCHSCREEN” at the back of the computer.
8. Connect each bedside station cable to the appropriate channel connector on the multi-I/O or expansion-I/O boards at the back of the computer and at the corresponding connector at the wall.

MONITOR SETUP

The monitor touchscreen must be calibrated at installation and each time the system has been moved. Use the following procedure to calibrate the touchscreen monitor.

The monitor video and touchscreen control cable must be connected and power connected and applied to the touchscreen monitor and computer before performing this procedure.

1. Turn on the monitor by pressing its power switch. Refer to the monitor operator's manual.
2. Turn on the computer by pressing the power switch on the computer front panel.
3. In necessary, adjust the monitor's display size and position. Refer to the monitor operator's manual.
4. Access the System Setup function screen and perform a touchscreen calibration. See Performing Touchscreen Calibration, page 52.

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CENTRAL STATION SETUP

Performance Verification
Patient Setup
Admitting a Patient or Changing Patient Data
Central Station Patient Alarm Settings
Setting Channel Standby Status
Setting SpO₂ Gain
Setting ECG Scale
Setting Default Waveform
Discharging a Patient
Transferring a Patient to a Different Bed

PERFORMANCE VERIFICATION

Before operating the *Oxinet II* monitoring system, performance should be verified by qualified service personnel following the procedures contained in the *Oxinet II* monitoring service manual.

PATIENT SETUP

All patient setup functions are done through the Patient Setup screen and subscreens. Click the bed button for the bed to be set up and click the Setup button at the bottom of the screen to display the Patient Setup screen. A typical Patient Setup screen is shown in Figure 9, page 26.

When a patient is to be monitored at the central station, patient data must be entered. Operating parameters also have to be set. Patient discharge and transfer are also accomplished using the patient setup screen and subscreens. If patient data needs to be changed, use the same procedures as if admitting the patient.

ADMITTING A PATIENT OR CHANGING PATIENT DATA

Use the following procedure to admit a new patient. This procedure is also used to change patient information that is already entered.

1. Click the Setup function button to display the Patient Setup screen.
2. Click the bed button of the bed into which a new patient is to be admitted or the bed button of the patient requiring a change in patient information.

3. Click the Admit button. The Enter Patient Name data entry screen appears titled as shown in Figure 38.

Note: Click the Exit button at any time to newly entered or changed data. Then click Yes to save changes you have made or click No to quit and make no changes to the patient data.

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1100A	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1000C	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1600E	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost

Figure 38: Patient Name Data Entry Screen

4. Click screen keyboard keys or buttons as needed to enter or change the patient name.

Notes: An external keyboard attached to the central station can be used to enter or change patient data. To click the screen button when using a touchscreen monitor, touch the screen on the button or key. When using a mouse, position the mouse pointer over the button or key on the screen and click any mouse button.

Click the on-screen Shift key to lock or unlock characters for entering capital letters.

The backspace button (a left arrow button on the right of the top row of keys) deletes the character to the left of the cursor. The DEL button deletes the character that the cursor is positioned over.

5. Click the Enter button after you have entered or changed the patient's name. The Enter Patient ID data entry screen is displayed.
6. Enter or change the patient's identification number (ID).
7. For radio-link systems, click the ENTER button after entering the patient's identification number. The Enter Remote ID screen is displayed. Skip to step 9.
8. For hard-wired systems, click the Enter button after entering the patient's identification number. When Patient Setup screen is displayed, patient setup is complete.
9. Enter or change the remote transceiver identification number that is shown on the radio transceiver tag at the bedside station to which the patient will be connected.
10. Click the Enter button after you have entered the remote transceiver ID number. When Patient Setup screen is displayed, patient setup is complete.

Note: If *Standby* is set to ON, set *Standby* to OFF on the Patient Setup screen so data can be received at the central station from the bedside station.

CENTRAL STATION PATIENT ALARM SETTINGS

Alarm settings at the central station consist of setting up three functions.

- The first function to be set is whether an audible indication is to be produced for alarm conditions reported by a bedside station.
- The second function is whether the central station automatically prints a patient status report when a particular alarm condition is reported by a bedside station.
- The third function is whether the central station automatically prints a patient waveform strip on the thermal printer or attached laser printer.

An alarm limit set at the bedside station is a value such that when the monitored patient parameter exceeds the set alarm limit value, an alarm is generated at the bedside station and reported to the central station through the communication link where it is indicated as a medical alarm. Bedside alarm limits cannot be changed from the central station. The bedside station monitor also reports

malfunctions to the central station where they are indicated as technical alarms.

The Print or the Audible function for certain central station alarms can be set to either to ON or OFF. The default setting of these functions is set in system setup. The default setting is active unless changed using the following procedure.

When Print is set to ON for a particular central station alarm, a laser printer connected to the central station automatically prints a record of patient trend data and the source of the alarm when that central station alarm occurs. When Print is set to OFF, the printer does not print automatically.

Note: The Print setting of the low and medium priority technical alarms *NIPB Error*, *Sensor Disc.*, *Check Sensor*, *ECG Noise*, *ECG Lead Off*, *ECG Cable Off*, *Resp Noise*, *Resp Lead Off*, and *Resp Cable Off* are permanently OFF and cannot be set to ON.

The Audible function is used to prevent or allow an audible alarm when a central station alarm condition occurs. When Audible is set to an audible indication is not heard when the alarm condition occurs. The visual alarm indicators continue to function regardless of whether the Audible setting is set to ON or to OFF.

Note: The Audible setting of the high priority medical alarm *No Pulse* and *Asystol* is permanently ON and cannot be set to OFF.

Whenever any alarm Audible setting is set to OFF, the bed button and the message display on the Patient Detail screen constantly display a flashing alarm silence symbol.

WARNING: Patient safety could be compromised if the Audible function is set to OFF which inhibits the audible indication of a patient alarm. Verify that patient alarms will still be acknowledged if the Audible function is set to OFF.

The Strip function for certain central station alarms can be set to either STRIP, LASER, or OFF. The default setting of these functions is set in system setup. The default setting is active unless changed using the following procedure.

When Strip is set to STRIP for a particular central station alarm, the internal thermal printer automatically prints a patient waveform when that alarm occurs.

When Strip is set to LASER for a particular central station alarm, the attached laser printer automatically prints a patient waveform when that alarm occurs.

When Strip is set to OFF no waveform printouts are automatically printed.

Use the following procedure to set central station alarm settings for an individual patient. This procedure is also used to change existing patient alarm settings.

1. Click the Setup function button to display the Patient Setup screen.
2. Click the bed button of the patient for whom you are setting or changing alarm settings.
3. Click the Alarm Settings button. The Alarm Settings screen is displayed, as shown in Figure 39.

Central Station Setup

1100A Cindi Wallace

Alarm Settings

Alarm	Print	Strip	Audible
No Pulse	OFF	OFF	ON
Pulse Lost	OFF	OFF	ON
SpO ₂ High	OFF	STRIP	ON
SpO ₂ Low	OFF	OFF	ON
Pulse High	OFF	OFF	ON
Pulse Low	OFF	OFF	ON
Syst. High	OFF	OFF	ON
Syst. Low	OFF	LASER	ON
Diast. High	OFF	OFF	ON
Diast. Low	OFF	OFF	ON

Pg Up ↑ Pg Dn ↓

Print Off Strip Off Audible On

Restore Defaults OK

Room	Patient	SpO ₂ %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1100A	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1000C	Ben Debone	96	97 ↓	21	138/99 (107)	SpO ₂ High
1600E	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost

Map List Waves Detail 2:48:31 PM 23-June-1996 Setup Silence ? Help Print

1000A 1400A 1000B 1400B 1000C 1400C 1000D 1400D 1000E 1500A 1000F 1500B 1100A 1500C 1100B 1500D 1100C 1600A 1100D 1600B 1200A 1600C 1200B 1600D 1200C 1600E 1200D 1600F 1300A XFER 1300B

Figure 39: Alarm Settings Screen

4. Use the Pg Up, Pg Dn, up-arrow, or down-arrow buttons to move the highlighted cursor over the alarm to be changed.
5. Click the Print button to toggle the Print alarm setting between ON and OFF. Click the Audible button to toggle the Audible alarm setting between ON and OFF. Click the Strip button to toggle the Strip alarm settings between STRIP, LASER, and OFF.
6. Repeat steps 4 and 5 for each alarm setting to be changed.
7. After you have finished setting the patient's alarm settings, click the OK button. The Patient Setup screen is then displayed.

Note: To restore system default Print, Strip and Audible patient alarm settings for the selected patient, click the Restore Defaults button on the alarm settings screen.

SETTING CHANNEL STANDBY STATUS

When it is necessary to temporarily disconnect a patient from the bedside station monitors, the patient's bed can be set in a standby state so that nuisance alarms do not occur at the central station. *Standby* status is helpful in situations such as when the patient needs to be temporarily removed for services out of the room.

A bedside station's *Standby* status can be set to ON or OFF. During normal operation while the bedside station monitors are connected to the patient, *Standby* is set to OFF and patient data is being exchanged normally on the communication channel for the bedside station. You can set *Standby* to ON when the patient is temporarily disconnected from the bedside monitors.

The central station ceases communicating with the bedside station and no alarms are initiated until *Standby* is returned to OFF. Use the following procedure to set the *Standby* status for a patient's bedside station.

Note: When *Standby* is set to OFF for a bed, patient data that was present prior to setting *Standby* to ON may be displayed and remain displayed for up to 2 minutes.

1. Click the Setup function button to display the Patient Setup screen. Refer to Figure 9, page 26.
2. Click the bed button of the patient for whom you are setting the *Standby* status.
3. Click the Standby button to toggle the *Standby* status and set the display in the window to the right of the button to show either ON or OFF. When the *Standby* status is set to ON, the letter "S" is displayed on the bed button of the channel. The channel *Standby* status remains as set until it is changed again.

SETTING SPO₂ GAIN

Setting the SpO₂ gain affects the amplitude at which the received plethysmograph signal is displayed on the Patient Detail screen and the Waves screen.

The gain can be set at X0.5, X1, X2, X3, and X4 multiples of the received signal. For example, the X0.5 setting multiplies the received signal by one half and the amplitude of the displayed waveform is one half that of the received signal. The X4 setting multiplies the received signal by four and the amplitude of the displayed waveform is four times larger than the received waveform.

Use the following procedure to set the gain for a SpO₂ signal from a patient's bedside station. Refer to Figure 9, page 26.

1. Click the Setup function button to display the patient setup screen.
2. Click the bed button of the patient for whom you are setting SpO2 gain.
3. Click the SpO2 Gain button to cycle through the SpO2 gain selections and set the display in the window to the right of the button to read X0.5, X1, X2, X3, or X4. The SpO2 gain remains as you set it until you change it again.

SETTING ECG SCALE

Setting the ECG Scale affects the amplitude at which the received ECG signal is displayed on the Patient Detail screen and the Waves screen. The waveform reference can be set at 2.5, 5, 10, 20, or 40 mm/mV. The displayed waveform is then referenced to the selected value.

Use the following procedure to set the ECG reference scale. Refer to Figure 9, page 26.

1. Click the Setup function button to display the patient setup screen.
2. Click the bed button of the patient for whom you are setting ECG reference scale.
3. Click the ECG Scale button to cycle through the ECG scale selections and set the display in the window to the right of the button to read 2.5, 5, 10, 20, or 40 mm/mV. The ECG reference scale remains as you set it until you change it again.

SETTING DEFAULT WAVEFORM

Setting the default waveform determines whether an ECG waveform or a plethysmograph waveform is displayed on the Patient Detail screen when the screen is initially accessed. This setting overrides the setting set as the system default waveform. Use the following procedure to set default waveform. Refer to Figure 9, page 26.

1. Click the Setup function button to display the patient setup screen.
2. Click the bed button of the patient for whom you are setting default waveform.

3. Click the Default Waveform button to cycle through the default waveform selections and set the display in the window to the right of the button to Pleth to set a plethysmograph waveform as the default waveform or display ECG for an ECG waveform as the default waveform. The default waveform remains as you set it until you change it again.

Note: For patients being monitored by an NPB-290, NPB-295, N-395, N-595, or N-3000 without ECG, set the waveform selection to Pleth.

DISCHARGING A PATIENT

When it is determined that a patient is no longer to be monitored by the *Oxinet II* monitoring system, such as, when the patient is discharged, the bedside station channel is set to accept a new patient by initiating the Discharge function as described below.

Caution: (N-3000 only.) When the New Patient function is initiated at the bedside station or the Discharge function is initiated at the central station, all patient information and all trend data for the patient stored in the central station is permanently deleted.

Use the following procedure to initiate the Discharge function at the central station. Caution: (N-3000 only.) When the New Patient/ Neonatal button at a bedside station monitor is pressed and held for 3 seconds, the Discharge function is also initiated at the central station for that patient. All patient information and all trend data for the patient stored in the central station are permanently deleted.

1. Click the Setup function button to display the Patient Setup screen.
2. Click the bed button of the patient to be discharged.
3. Click the Discharge button. A window pops up to remind you that all patient information and data will be cleared and to ask you if you want to clear all information.
4. Click the No button if you do not want to clear all data and abort the discharge. Click the Yes button to clear all patient information and stored trend data. If you click the No button, the Discharge function is terminated, all patient data is retained, and the Patient Setup screen is displayed.

If you click the Yes button, all data for the selected patient is deleted, "New Patient" will replace the patient's name, and the Patient Setup screen is displayed.

TRANSFERRING A PATIENT TO A DIFFERENT BED

Use the following procedure to transfer a patient to a different bed.

Note: The bed into which the patient is being transferred must have had the discharge function performed on it and the central station should not be receiving data from the bedside station.

1. Click the Setup function button to display the Patient Setup screen. Refer to Figure 9, page 26.
2. Click the bed button of the bed from which the patient will be transferred. Click the Transfer button. A window is displayed telling you to click the bed button for the bed to which the patient is to be transferred.
3. Click the bed button for the bed to which the patient is to be transferred. A window displays a message if the bed is already in use, in which case, click another bed button. If the bed in a radio-link system has had the discharge function performed on it, a window is displayed asking if you want to transfer the radio with the patient.
4. Click Yes if the currently selected bedside station and its radio transceiver are to be transferred along with the patient. Click NO if the patient is to be connected to a different bedside station and radio transceiver in the new bed.

START-UP AND USE

- Overview of Operation
- Turning on the Central Station
- Turning on the Bedside Station
- Using Bed Buttons
- Using On-Screen Help
- Using the Map Screen
- Using the List Screen
- Using the Waves Screen
- Using the Patient Detail Screen
- Using the Patient Setup Screen
- Printing Patient Data

OVERVIEW OF OPERATION

For the procedures in this section, it is assumed that the *Oxinet II* monitoring system is set up as described in the *Setup* section.

The *Oxinet II* monitoring system software runs on a computer system that is using the disk operating system (DOS). In the typical operation of the *Oxinet II* monitoring system, you will primarily use any one of the following *Oxinet II* monitoring system operating screens: the Map screen, the List screen, the Waves screen, and the Patient Detail screen. A general description of each of these screens is provided in the *Controls, Indicators, and Screens* section.

Refer to the operator's manuals for the NPB-290, NPB-295, N-395, N-595, or N-3000 patient monitor and the N-3100 blood pressure monitor for detailed setup and operating instructions for these monitors.

This section contains instructions for turning on the central station and for turning on the monitors at the bedside station.

TURNING ON THE CENTRAL STATION

To turn on the central station, press the power switch on the front panel of the central station computer (see Figure 40). The *Oxinet II* monitoring system software is loaded automatically.

The central station performs a short diagnostic test and within 20 seconds, the Map screen is displayed. A typical Map screen is shown in Figure 5, page 22. The central station establishes communication with all bedside stations that are turned on. Once communication is established, the *Oxinet II* monitoring system is ready to use.

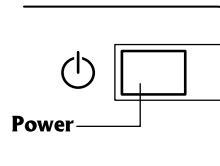


Figure 40: Turning On the Central Station

TURNING ON THE BEDSIDE STATION

NPB-290, NPB-295, N-395, N-595

For the NPB-290, NPB-295, N-395, and N-595 bedside stations to communicate with the central station, the NPB-290, NPB-295, N-395, and N-595 must be powered by AC power. In radio-link bedside stations, the radio must also be powered by AC power.

To turn on the NPB-290, NPB-295, N-395, or N-595, press the Power On/Off Button. See Figure 41 through Figure 44. Refer to the Operator's manual for the NPB-290, NPB-295, N-395, or N-595 for detailed operating procedures.

Note: Turn the bedside station off before connecting a remote transceiver.

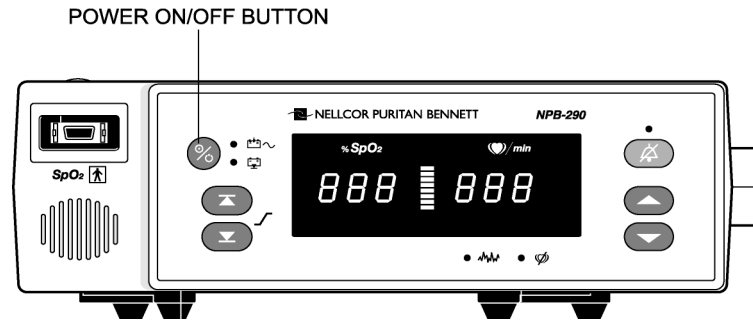


Figure 41: NPB-290 Power On/Off Button

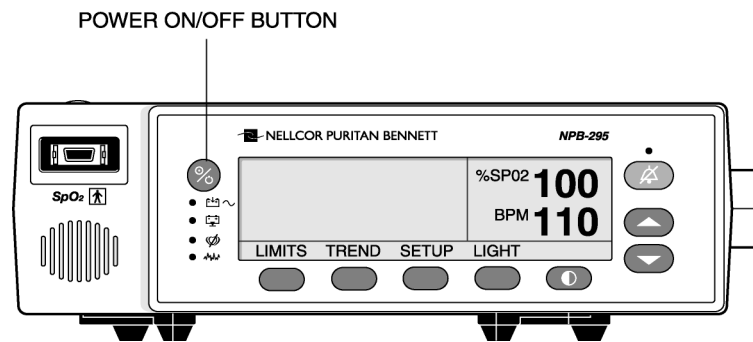


Figure 42: NPB-295 Power On/Off Button

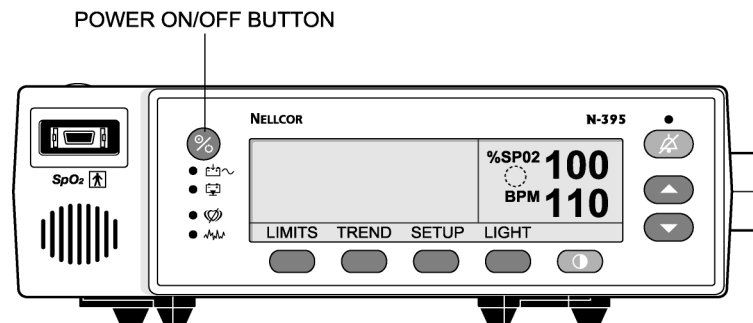


Figure 43: N-395 Power On/Off Button

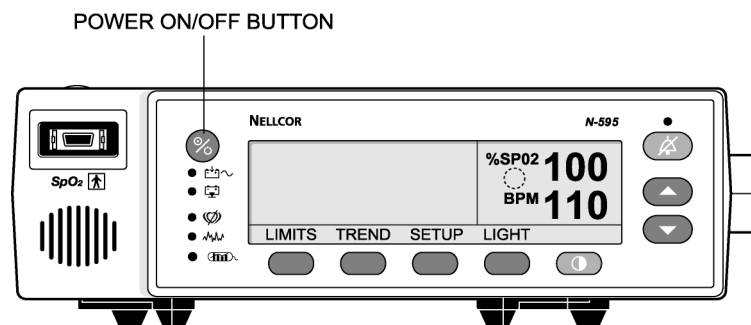


Figure 44: N-595 Power On/Off Button

N-3000

For the bedside station to communicate with the central station, the N-3000 must be connected to an SPS external power supply, a PSS-1 power supply or an N-3200 display/printer connected to AC power and turned on (see Figure 45).

To turn on the N-3000, the N-3100, and the N-3200, press the On/Standby button on each monitor. The On/Standby button is located in the upper right corner of the front panel of the monitors. Refer to the operator's manual for each of these monitors for detailed operating procedures.

Note: Turn the bedside station off before connecting a remote transceiver.

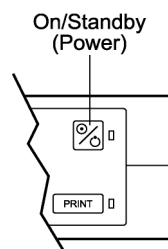


Figure 45: Turning On the N-3000 Series Bedside Station Monitors

USING BED BUTTONS

When you click a bed button, the button appears as if it has been pressed down and the number on the button face changes from

white to black. This indicates that the bed is now selected for further operations or functions. The bed remains selected until another bed button is clicked.

The letter "S" is displayed on a bed button when a bed is in standby.

For an individual bed, if one or more patient alarm settings have Audible set to OFF, the alarm silence symbol continuously flashes on the bed button. If no patient alarm settings have Audible set to OFF, the alarm silenced symbol is displayed for the duration of the alarm silence period set in system setup when an alarm has been silenced for the bed.

Using Bed Buttons to Select Patient Displays

On the Patient Detail screen and the Patient Setup screen, click the bed button to display data for the patient in that bed.

Using Bed Buttons to Silence Alarms

When a patient alarm condition occurs, the bed number button of the affected patient begins to flash in the color relative to the priority of the alarm.

To silence a patient alarm, click the flashing bed button, then click the Silence function button. The alarm is silenced for the duration of the alarm silence period set in system setup and the bed button changes to a solid color.

If no patient alarm settings have Audible set to OFF, the bed button displays a silence symbol. If one or more patient alarm settings have Audible set to OFF, the alarm silence symbol continuously flashes on the bed button.

Note: Whenever a bed button is clicked to silence an alarm, that bed button is selected and that bed becomes the active bed. For example, if the Patient Detail screen or the Patient Setup screen is displayed for one patient and you click a bed button to silence a patient alarm for another bed, the data displayed on these screens changes to that of the bed button that was clicked. Also subsequent actions on the Waves screen will be for the bed associated with the bed button that was clicked.

USING ON-SCREEN HELP

If you need a reminder on how to operate a feature of the *Oxinet II* monitoring system, you can click the Help function button at the bottom of the screen. A Help screen applicable to the operating screen or function currently in use is displayed. If you need more information, you can click the Index button to display the help topics index screen as shown in Figure 10, page 27. You can then click a topic to display specific detailed information about the topic.

USING THE MAP SCREEN

Anytime the Map function button is clicked, the Map screen is displayed. A typical Map screen is shown in Figure 5, page 22. The Map screen for your *Oxinet II* monitoring system contains a map in the upper left part of the screen that is custom designed to match the floor plan of the area covered by your *Oxinet II* monitoring system. A box for the central station is shown on the map in the appropriate location with the words *Central Station* in it.

The map will also contain boxes for each of the patient beds monitored by the *Oxinet II* monitoring system. When a bed box is clicked on the Map screen that bed will become the active bed and the Patient Detail screen for that bed will be displayed. Each active bed box contains the bed number and a colored dot in the upper right corner of the box. The presence and color of this dot indicates the alarm status of monitored patient conditions as listed in Table 5.

Table 5: Description of Color Dots in Bed Box

Dot Color	Indicated Condition
Solid Gray	Patient is being monitored, no alarms.
Flashing Red	Patient condition is causing a high priority medical alarm and/or there is a high priority technical alarm and the alarm is <i>not</i> silenced.
Solid Red	Patient condition is causing a high priority medical alarm and/or there is a high priority technical alarm and the alarm <i>has been</i> silenced.

Table 5: Description of Color Dots in Bed Box

Dot Color	Indicated Condition
Flashing Yellow	Patient condition is causing a medium or low priority medical or technical alarm and the alarm is <i>not</i> silenced.
Solid Yellow	Patient condition is causing a medium or low priority medical or technical alarm and the alarm <i>has been</i> silenced.
Flashing Blue	This is a latched alarm. A high, medium, or low medical or technical alarm had occurred and was not silenced. The alarm is no longer active.
No dot	The bed is in standby and patient parameters are not being displayed or monitored by the central station.

When a monitored patient parameter exceeds a limit set at any bedside monitor, an alarm sounds at the central station and the dot in the bed box where the alarm condition has occurred flashes. To silence the alarm at the central station, click the flashing bed button and then click the Silence function button at the bottom of the screen.

The audible alarm is silenced for that bed for the amount of the time set as the alarm silence period in system setup. The bed button and the dot in the bed box on the map stop flashing, but will remain a solid color until the alarm condition no longer exists. If no patient alarm settings have Audible set to OFF, the bed button displays a silence symbol.

If the alarm silence period elapses and the condition that caused the alarm is still present, the bed button and the dot in the bed box on the map start flashing again, the alarm sounds again at the central station and, if no patient alarm settings have Audible set to OFF, the alarm silence symbol disappears.

To silence this alarm, click the bed button and then click the Silence function button at the bottom of the screen. The bed button displays a silence symbol. If one or more patient alarm settings for the bed have Audible set to OFF, the alarm silence symbol continuously flashes on the bed button.

If the condition that caused the alarm goes away while the alarm is silenced, the bed button and the dot in the bed box on the map return to solid gray. If no patient alarm settings have Audible set to OFF, the silence symbol disappears from the bed button.

If another alarm condition of a higher priority is sent from the bedside station while the central station alarm is silenced, the alarm for the new condition sounds. If alarms have been silenced at the bedside station, new alarms will not be sent to the central station until the alarm silence period set at the bedside station has elapsed. The silence symbol disappears from the bed button if no patient alarm settings have Audible set to OFF, and the bed button and the dot in the map bed box flash with the color of the higher priority alarm.

If one or more patient alarm settings for the bed have Audible set to OFF, the alarm silence continuously flashes on the bed button. To silence this alarm, click the flashing bed button and then click the Silence function button at the bottom of the screen.

The Map screen also displays the Patient Alarm List which is described in *Controls, Indicators, and Screens*, page 15.

USING THE LIST SCREEN

Anytime the List function button is clicked, the Patient List screen is displayed showing a list of all monitored beds arranged in the same order as the bed buttons. A typical Patient List screen is shown in Figure 6, page 23.

Each list entry shows the patient's bed number, name, current measured parameters, and alarm status. The number in the Room column corresponds to the bed number. Communication status or patient alarm messages are displayed in the status column.

When multiple alarm conditions exist for a patient, only the highest priority alarm is displayed. If multiple alarms of equal priority exist, the messages in the status column cycle through the alarm messages at 1-second intervals. The word *Standby* is displayed in the status column if a bed is in standby status.

When a patient alarm is detected by the central station, a status message indicating the parameter causing the alarm is displayed, as described in Figure 4, page 21.

Table 6: Patient List Alarm Parameter and Status Display

Status Message Display	Indicated Condition
Solid White Dashes	(Parameters only) Parameter values have not been received from the bedside station.
Solid White	For patient parameters within acceptable ranges that are not causing an alarm condition and for the Standby message.
Flashing Red	Parameter and message flash red when a high priority medical or technical alarm has been detected and the alarm <i>has not</i> been silenced.
Solid Red	Parameter and message are solid red when a high priority medical or technical alarm has been detected and the alarm <i>has</i> been silenced.
Flashing Yellow	Parameter and message flash yellow when a medium or low priority medical or technical alarm has been detected and the alarm <i>has not</i> been silenced.
Solid Yellow	Parameter and message flash yellow when a medium or low priority medical or technical alarm has been detected and the alarm <i>has</i> been silenced.
Flashing Blue (Only if alarm latching is set)	Parameter and message flash blue when a medical or technical alarm has been detected and the alarm condition has ceased before it has been silenced and the alarm indication has been latched.

USING THE WAVES SCREEN

The Waves screen is displayed when you click the Waves function button. Use the Waves screen to display up to eight individual patient plethysmograph or ECG waveforms at one time. A typical Waves screen is shown in Figure 7, page 24.

Any one of five Waves screen pages can be displayed, each with eight waveform areas for a maximum total of 40 waveforms. Click the 1, 2, 3, 4, or 5 button below the waveforms to display the corresponding page.

The top part of each active waveform area displays the patient's bed number and name and their plethysmograph or ECG waveform. At the bottom of each waveform area is a dark gray horizontal bar that contains the currently measured values, if available; refer to Figure 7, page 24. If blood pressure values are not available, dashes are displayed for the values. The word *Standby* is displayed in this bar when the bed is in standby and no waveform is displayed.

Table 7: Wave Screen Display Parameters Available

Unit	NPB-290, NPB-295, N-395, and N-595	N-3000	N-3100
SpO2	Yes	Yes	No
Pulse Rate or Heart Rate	Yes	Yes	Yes
Pleth Waveform	Yes	Yes	No
ECG Waveform	No	Yes	No
Blood Pressure	No	No	Yes
Respiration Rate	No	Yes	No
<p>Note: N-3100 Pulse Rate – The N-3100 must have an N-3000 stacked with it in order to have this rate supplied from the N-3100.</p> <p>Note: ECG Waveform and Respiration Rate – This information is only available if the <i>Oxinet II</i> system is in the four-parameter mode and the stacked N-3000 equipment has the capability to monitor the parameters.</p>			

Only one waveform for a patient, either the plethysmograph waveform or the ECG waveform, can be displayed at one time on a

single Waves screen page. However, the patient's ECG waveform or plethysmographic waveform can be set up to be displayed on one Waves screen page and his or her ECG waveform or plethysmographic waveform can be set to be displayed on any other Waves screen page.

Finding a Waveform

To quickly move to the Waves screen page that contains a patient's waveform, click the bed button of the patient, then click the Find button below the waveform areas. The Waves screen page that contains the first occurrence of a patient's waveform is displayed.

Each time you click the Find button, the next page that contains either of the patient's waveforms is displayed. If none of the selected patient's waveforms has been assigned to a waveform area on another page, or if it is only on the currently displayed page, the displayed page does not change.

Deleting a Patient's Waveform from a Waveform Area

To delete a patient's waveform from a waveform area, click the Delete button below the waveform areas, then click the waveform area of the patient's waveform to be deleted. The patient will continue to be monitored even if his or her waveform is deleted from the Waves screen.

Assigning a Patient's Waveform to a Waveform Area

To assign a patient's plethysmograph or ECG waveform to a waveform area, click the desired bed button, then click the Pleth Assign or ECG Assign button, then click the desired empty waveform area. If the waveform area is empty, it will then display the patient's bed number and name, the plethysmograph waveform, and monitored parameters for the selected bed.

If the selected waveform area already is displaying another patient's waveform when the area is clicked, a prompt appears asking if the waveform area is to be reassigned. Click Yes to replace the existing waveform with the new one. Click No to leave the existing waveform displayed in the waveform area.

If a patient's waveform is currently displayed on a Waves screen page and an attempt is made to assign one of that patient's waveforms again, a white border will be displayed around the

patient's currently displayed waveform and all displayed waveforms will remain unchanged.

To change the waveform from either the plethysmograph or ECG waveform to the other waveform, the existing waveform must first be deleted from the waveform area and then the desired new waveform assigned.

Freezing a Waveform

The movement and update of any patient's waveform(s) can be frozen if Freeze has been set to ON in system configuration. To freeze a patient's waveform on a Waves screen page, click the waveform area of the patient. To allow the waveform to again move and be updated, click the frozen waveform area again or select another Waves screen page. When a waveform is frozen, the word "Freeze," and the patient's bed number, and name flash in the waveform area.

USING THE PATIENT DETAIL SCREEN

Click the bed button of the patient you want to display on the Patient Detail screen, then click the Detail function button. The Patient Detail screen is displayed for the bed button that is selected. A typical Patient Detail screen is shown in Figure 8, page 25.

This screen displays the patient's plethysmograph or ECG waveform, the patient's measured parameters, and status messages.

The patient's bed number, name, and identification number are displayed at the top of the patient detail area. Advisory messages are also displayed in this area. Advisory messages indicate the operating mode of the bedside station.

The word "Neonatal" is displayed when the N-395, N-595, or N-3000 is in neonatal mode and the area is blank when the N-395, N-595, or N-3000 is in adult-pediatric mode. Pulse Search is displayed when the NPB-290, NPB-295, N-395, N-595, or N-3000 is in the pulse search mode. Motion is displayed when patient motion is interfering with the SpO₂ measurements. ECG Noise or Resp Noise is displayed when patient motion is interfering with the ECG or respiration measurements, respectively.

Below this data, current alarm messages are displayed using colors and flash rates for alarms as described in *Alarm Priority Colors*

and Flash Rate. The word *Standby* is displayed in white in this area when the bed is in standby.

The current measured values are displayed from left to right below the message. Refer to Table 7 for available values. Pulse rate is identified by the letters PR to the right of the displayed value, and heart rate is identified by the letters HR. N-3100 derived blood pressure is displayed as systolic/diastolic and mean blood pressure values. If any measured values are not available, dashes are displayed.

Upper and lower alarm limits that are set at the bedside station are displayed below each measured patient parameter. The number on top is the upper alarm limit. The number on the bottom is the lower alarm limit. The elapsed time in minutes since the last N-3100 blood pressure measurement is displayed under the word Minutes between the respiration and blood pressure alarm limit displays.

When the bed is in standby, there is no waveform or other data displayed.

Note: If you click an unselected bed button while the Patient Detail screen is displayed, a new Patient Detail screen for that patient is displayed.

Freezing the Waveform Display

The movement and update of the patient's displayed waveform can be frozen for evaluation if Freeze has been set to ON in system configuration. To freeze the waveform, click the waveform area. The word "Freeze" is displayed in the waveform area. To allow the waveform to again move and be updated, click the frozen waveform area again.

Displaying Graphical Patient Trend Screen

Click the Trends Graph button on the Patient Detail screen to display a graphical representation of the patient's trend data. The Graphical Trends screen is displayed. A typical Graphical Trends screen is shown in Figure 46. The Patient Alarm List is not displayed while the Graphical Trends screen is displayed.

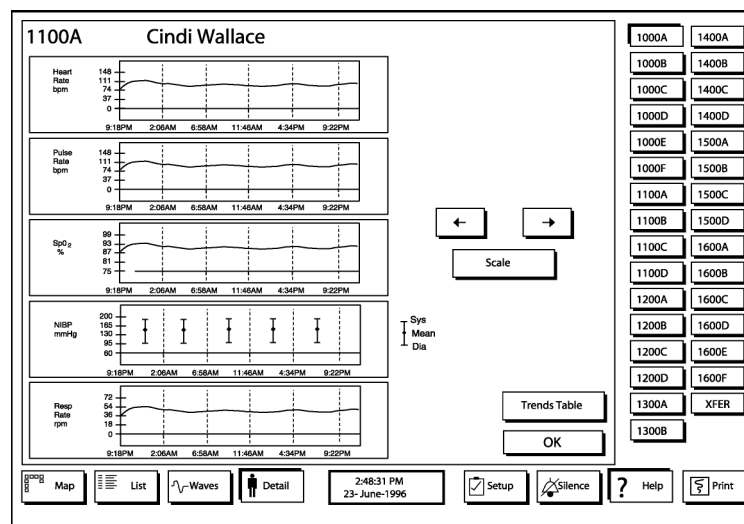


Figure 46: Typical Graphical Trends Screen

The Graphical Trends screen contains, from top to bottom, graphical trend plots of heart rate, pulse rate, SpO₂, NIBP measurements, and respiration rate.

The vertical scale on each graphical trend display shows the values of the measured parameter. The selected time scale is displayed horizontally on each graphical display. The beginning time of the time displayed is shown on the left and the ending time of the time scale is shown on the right.

When the Trend Data screen is initially displayed, a time scale of 24 hours is the selected time scale for the graphical trend displays. This scale remains in effect until another time scale is selected. The time scales of the trend display that may be selected are 15 or 30 minutes or 1, 2, 4, 8, 12, or 24 hours. To select a different time scale, click the Scale button. A window appears with a list of available selections.

Click the Up Arrow or the Down Arrow button as needed, or the desired time scale itself, to highlight the desired time scale and click the OK button. All graphical trend displays assume the selected time scale and the right-hand side of each display is referenced to the current time.

Click the Left Arrow and the Right Arrow button to move the displayed time window backward or forward in time, respectively, by one-half the selected time scale. When 24 hours is the displayed time scale, the time window does not move.

For each blood pressure measurement, the NIBP graphical display shows a vertical bar with a horizontal bar on top and bottom and a diamond between these horizontal bars. The top horizontal bar is the systolic blood pressure measurement. The bottom horizontal bar is the diastolic blood pressure measurement. The diamond on the vertical bar is the mean blood pressure measurement (See Figure 47).

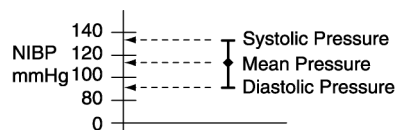


Figure 47: NIBP Graphical Display Format

At any time, regardless of the screen displayed, you can click the Print function button to print the patient's graphical data and all tabular NIBP data for the patient whose bed button has been clicked and selected. See *Printing Patient Data*, below. The patient data is printed on the laser printer connected to the central station.

Note: The time scale for the graphical trend printout is set up in system setup and may not be the same as that displayed on the Graphical Trends screen. All NIBP tabular data is printed out.

Click the OK button to exit the Graphical Trends screen and return to the Patient Detail screen. Click the Trends Table button to display the NIBP Tabular Trends screen.

Displaying NIBP Tabular Trends Screen

Click the Trends Table button on the Patient Detail screen or the Graphical Trends screen to display a tabular listing of the patient's NIBP data. The NIBP Tabular Trends screen is displayed. A typical NIBP Tabular Trends screen is shown in Figure 48. The Patient Alarm List is not displayed while the NIBP Tabular Trends screen is displayed.

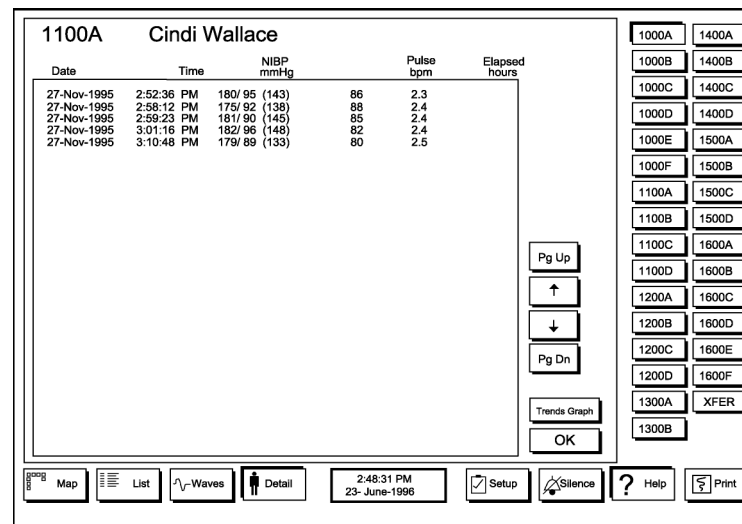


Figure 48: Typical NIBP Tabular Trends Screen

The tabular listing of blood pressure lists all measured and stored blood pressure values. Each measurement shows the date and time in the format set up in system setup, the NIBP measurement in the format Systolic/Diastolic (Mean), the N-3100 measured pulse rate, and the elapsed time in hours since the measurement was taken. An asterisk (*) to the left of a displayed measurement indicates that system date and time have been adjusted since that measurement was taken.

Note: Whenever an NIBP blood pressure value of "-1" is shown in any patient data display, it is an indication that patient data is not available from N-3100 at the bedside station for that patient. Dashes are also used to indicate that patient data is not available.

At any time, regardless of the screen displayed, you can click the Print function button to print the patient's graphical data and all tabular NIBP data for the patient whose bed button has been clicked and selected. See *Printing Patient Data*, below. The patient data is printed on the laser printer connected to the central station.

Click the OK button to exit the NIBP Tabular Trends screen and return to the Patient Detail screen. Click the Trends Graph button to display the Graphical Trends screen.

USING THE PATIENT SETUP SCREEN

The Patient Setup screen is used to enter patient information such as name and identification number when a patient is admitted to a bed monitored by the *Oxinet II* monitoring system. This screen is also used to discharge a patient and clear all monitored patient parameters stored in the memory. Alarm audibility settings, print on alarm settings, standby status, SpO₂ channel gain, and ECG channel gain are also set on this screen. The Patient Setup screen is shown in Figure 9, page 26. Refer to the *Central Station Setup* section, page 65, for detailed procedures for using this screen.

Caution: Initiating the Discharge function causes all patient information and all trend data stored in the central station for the patient to be *permanently deleted*.

PRINTING PATIENT DATA

Laser Printer

You can print a patient summary report on a laser printer connected to the central station computer. A typical printed patient summary report is shown in Figure 49. To print a patient data summary report, click the Print function button. The first page of the patient summary report contains a demographic header, graphic trends of heart rate, pulse rate, SpO₂ percent, NIBP measurements, and respiration rate.

The vertical scale on each graphical trend shows the values of the measured parameter. The time scale selected in system setup is displayed horizontally on each graphical display. The beginning time of the time displayed is shown on the left. The time when the printout was initiated is shown on the right.

For each blood pressure measurement, the NIBP graphical display appears in the printout as it does on the Graphical Trends screen. See *Displaying Graphical Patient Trend Screen*, page 96.

Subsequent pages of the report contain a demographic header, and a tabular listing of all measured and stored blood pressure values.

Each measurement shows the date and time in the format set up in system setup, the NIBP measurement in the format Systolic/Diastolic (Mean), the measured pulse rate, and the elapsed time in hours since the measurement was taken.

An asterisk (*) to the left of a displayed measurement indicates that system date and time were adjusted since that measurement was taken.

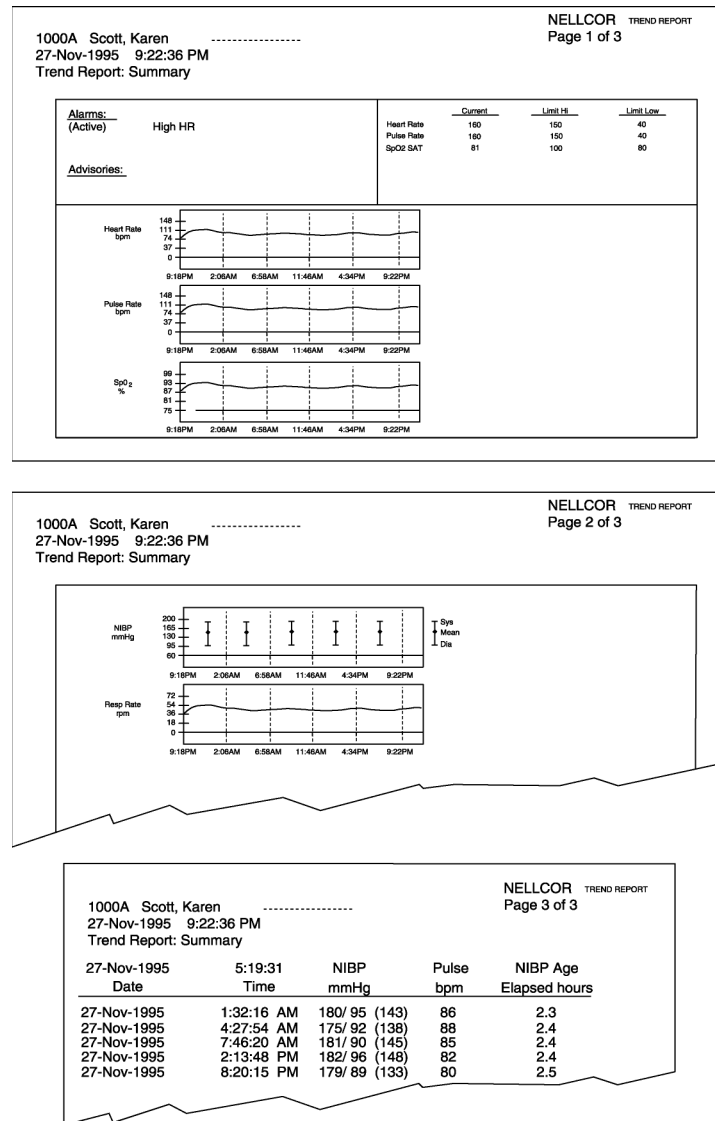
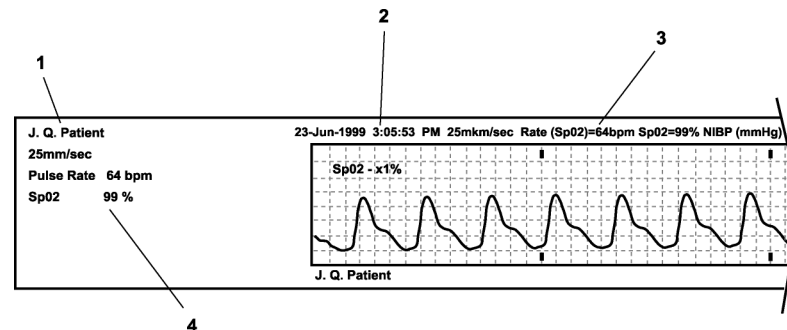


Figure 49: Typical Printed Patient Summary Report

Thermal Printer

Units capable of receiving ECG and respiratory rate can be equipped with an optional thermal printer. The thermal printer provides the capability of printing data during an alarm condition, ECG or plethysmographic waveforms, or trend information.

With the Strip print function set to STRIP, a patient waveform automatically prints on the (optional) internal thermal printer at the central station when the selected alarm is received from a bedside monitoring unit. Refer to Figure 50.



1. Patient Name
2. Date and Time
3. Current Vital Signs
4. Current Vital Signs

Figure 50: Typical Thermal Printer Printout

TROUBLESHOOTING AND MAINTENANCE

- Overview
- Operator Troubleshooting
- Operator Maintenance
- Determining Software Version
- Obtaining Technical Assistance

OVERVIEW

Troubleshooting and maintenance of the *Oxinet II* monitoring system and the central station are performed at the operator's level and at the service technician's level. *Oxinet II* monitoring system operator troubleshooting and maintenance are described in this section. Refer to the *Oxinet II* monitoring system service manual for service technician level troubleshooting and maintenance procedures.

For bedside station operator troubleshooting and maintenance instructions, refer to the appropriate operator's manual for the NPB-290, NPB-295, N-395, N-595, N-3000, N-3100, or N-3200. For service technician level troubleshooting and maintenance, refer to the service manual for the NPB-290, NPB-295, N-395, N-595, N-3000, N-3100, or the N-3200 directions for use.

Operator maintenance consists of external cleaning of *Oxinet II* system components and changing the paper in the thermal printer.

OPERATOR TROUBLESHOOTING

In the event of technical difficulties, operator troubleshooting is limited to the activities listed in Table 8. This table presents typical problems, probable causes, and suggested actions to correct the problems. For any problems not listed in Table 8, contact your system administrator or your facility clinical engineer or Nellcor's Technical Services Department.

Table 8: Troubleshooting Table

Problem	Possible Cause	Corrective Action
Central station does not turn on or has shut off unexpectedly	AC power cord is unplugged or disconnected from the uninterruptible power supply (UPS), the computer, or the touchscreen monitor	Check that power cord is plugged into the UPS, the wall receptacle, the computer, and the touchscreen monitor. Plug in power cords as needed.
	The main power switch on the UPS is turned off.	Check the UPS main power switch is turned on. Turn on if necessary.
	The power switch on the rear panel the central station computer is turned off.	Check the power switch on the rear panel of the central station computer. Turn on if necessary.
	AC power is off at the wall receptacle	Call your facility clinical engineer to check that power is available at the wall receptacle and that circuit breakers for the AC power circuit are on.

Table 8: Troubleshooting Table

Problem	Possible Cause	Corrective Action
Communication link is lost or intermittent between a bedside station and the central station	Power to the bedside station is lost or intermittent	NPB-290, NPB-295, N-395, N-595 – Check that power cord is securely plugged into the monitor and into the wall receptacle. N-3000 - Check that power supply AC power cord is securely plugged into the power supply and into the wall receptacle and that power is available at the receptacle. Plug in power cord as needed. Check that power supply is securely connected to the bedside station. Reconnect power supply as needed.
	Communication cable is disconnected at the bedside station	Check communication cable connections at the bedside station. Reconnect cable as needed.
	Communication cable is disconnected at the central station.	Check communication cable connections at the central station. Reconnect cable as needed.

Table 8: Troubleshooting Table

Problem	Possible Cause	Corrective Action
	There is radio frequency interference between the central station and the bedside station	Move the bedside station and if that does not correct the problem, contact your facility clinical engineer or Mallinckrodt's Technical Services Department.
	Intermittent communication link	See Corrective Action for <i>Communication link is lost or intermittent between a bedside station and the central station</i> above.
The central station resets and restarts unexpectedly	There is a problem with the central station computer	Contact your facility clinical engineer or Mallinckrodt's Technical Services Department.
	AC power cord connection(s) are loose at the central station	Check that power cords are securely plugged into the back of the central station computer, the UPS, and the wall receptacle. Plug in power cords as needed.

OPERATOR MAINTENANCE

Operator maintenance on the central station consists of routine cleaning and changing the thermal printer paper as needed.

For instructions on troubleshooting and maintenance, at the bedside station, by the operator, refer to the appropriate operator's manual for the NPB-290, NPB-295, N-395, N-595, N-3000, N-3100, or N3200.

For instructions on troubleshooting and maintenance, at the bedside station, by a service technician, refer to the service manual for the NPB-290, NPB-295, N-395, N-595, N-3000, N-3100, or N-3200.

Cleaning

Caution: Do not immerse any component of the central station in liquid or use caustic or abrasive cleaners. Do not spray or pour any liquid on the central station or its accessories. Do not allow any liquid to come in contact with the power connector, controls, or switches. Do not allow any liquid to penetrate connectors or openings in the chassis.

To clean the central station computer, printer, and monitor case, dampen a cloth with a commercial, nonabrasive cleaner and wipe exposed surfaces lightly. If a liquid is accidentally spilled on any component of the central station, contact your facility clinical engineer.

Changing Thermal Printer Paper

Use the following procedure to change the thermal printer paper. Refer to Figure 51.

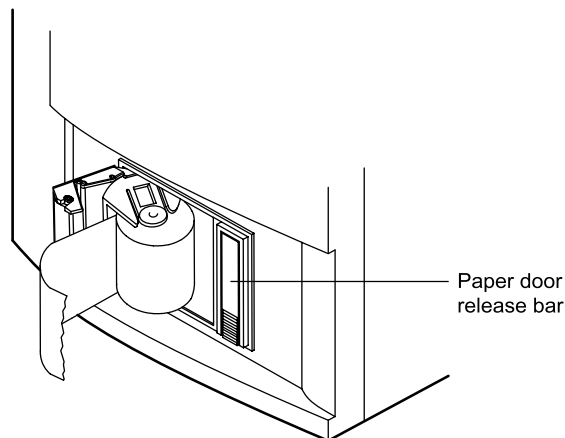


Figure 51: Changing Thermal Printer Paper

1. Press bottom right side of the paper door release bar at the top of the thermal printer to open the printer paper door.
2. Remove any empty paper roll core.
3. Position new roll of thermal printer paper in roll bracket with four inches of paper extending off of roll.
4. Hold on to free end of paper and swing recorder paper door up.
5. Push on paper door until it latches in place.
6. Tear off excess paper.

DETERMINING SOFTWARE VERSION

To display the version of the installed software, click the Setup function button to display the Patient Setup screen. Then click the System button at the top of the screen to display the System Password Entry screen. Then click the System Information button to display the System Information screen.

A typical radio-link System Information screen is shown in Figure 52. A typical hard-wired System Information screen is shown in Figure 53. Refer to the *Oxinet II* monitoring system service manual for a description of the information displayed on this screen.

System Information:

VER: 1.10F November 20, 1996
P/N: NCSW-R30
LIB: V3.10 November 20, 1995
Sound Board Software Version: 1.0
Sound Board Firmware Version: 1.0
Sound Board Serial Number: 512011
Sound Board Address/IRQ: DF000/9
Transceiver Firmware Version: 72
IRQ: 10
CPU: Pentium

OK

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1100A	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High

↑
↓

Map List Waves Detail 2:48:31 PM 23-June-1995 Setup Silence ? Help Print

1000A 1300B
1000B XFER
1000C
1000D
1000E
1000F
1100A
1100B
1100C
1100D
1200A
1200B
1200C
1200D
1300A

Figure 52: Typical Radio-Link System Information Screen

System Information:

VER: 1.10A November 20, 1996
P/N: NCSW-W16X
LIB: V3.10 November 20, 1995
I/O Board Software Version: 1.0
I/O Board Type: Multi-Standard
I/O Board 1:
Firmware Version: 1.0
Serial Number: 510005
Address/IRQ: DF00019
I/O Board 2:
Firmware Version: 1.0
Serial Number: 643301
Address/IRQ: DA0A003
CPU: Pentium

OK

Room	Patient	SpO2 %	Pulse BPM	Resp RPM	NIBP mmHg	Status
1100A	Cindi Wallace	100	92 ↓	20	139/99 (107)	Pulse High
1000C	Ben Debone	96	97 ↓	21	138/99 (107)	SpO2 High
1300B	John Sanborn	94	92 ↓	19	139/99 (107)	Pulse Lost

↑
↓

Map List Waves Detail 2:48:31 PM 23-June-1996 Setup Silence ? Help Print

1000A 1300B
1000B XFER
1000C
1000D
1000E
1000F
1100A
1100B
1100C
1100D
1200A
1200B
1200C
1200D
1300A

Figure 53: Typical Hard-Wired System Information Screen

OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, call Nellcor's Technical Services Department or contact your local Nellcor representative. Refer to this manual's inside front cover for locations and phone numbers. The service manual includes information required by qualified service personnel when servicing the *Oxinet II* monitoring system.

SPECIFICATIONS

Electrical Characteristics
Physical Characteristics
Environmental
Operational Characteristics
Radio-Link Transceivers Characteristics
Laser Printer Minimum Requirements
Agency Regulatory Notices
Component and System Labels

This section contains specifications for components of the central station and the bedside station remote radio transceiver. Requirements for the facility-provided laser printer are also provided.

ELECTRICAL CHARACTERISTICS

Central Station External AC Input Voltage/Current

115 Vac, 60 Hz, 3.5 A or
230 Vac, 50 Hz, 2 A

Protection of Remote Radio Transceiver from Defibrillation

The remote radio transceiver shall not be damaged by defibrillation and shall return to normal operation within 15 seconds of defibrillation.

PHYSICAL CHARACTERISTICS

Dimensions

Computer

22.8 cm (9 in.) x 38.1cm (15 in.) x 43.2 cm (17 in.)

15-Inch Monitor

Depends on the monitor supplied with your system. Monitors are purchased from different manufacturers.

Specifications**19-Inch Monitor**

Depends on the monitor supplied with your system. Monitors are purchased from different manufacturers.

Uninterruptible Power Supply

15.0 cm (6.0 in.) x 9.0 cm (3.4 in.) x 33.0 cm (13.1 in.)

Bedside Station Radio Transceiver

12.5 cm (4.92 in.) x 6.7 cm (2.64 in.) x 3.0 cm (1.18 in.)

Weight**Computer**

18 kg (40 lbs)

15-Inch Monitor

Depends on the monitor supplied with your system. Monitors are purchased from different manufacturers.

19-Inch Monitor

Depends on the monitor supplied with your system. Monitors are purchased from different manufacturers.

Uninterruptible Power Supply

8.2 kg (18 lbs)

Bedside Station Radio Transceiver

0.18 kg (6.6 oz)

ENVIRONMENT**Temperature****Operating**

+10° C to +35° C (+50° F to +95° F)

Shipping/Storage (in sealed shipping container)

-20° C to +60° C (-4° F to +140° F)

Relative Humidity**Operating**

15% RH to 85% RH (noncondensing)

Shipping/Storage (in sealed shipping container)

95% at 35° C (95° F) maximum, non-condensing

Central Station Ventilation and Cabling Requirements

All components of the central station should have a minimum of 1.5 inch clearance around top, sides, back, and front for ventilation. No central station component should be installed in an enclosed cabinet. A minimum of 4 inches is required behind the computer to accommodate cabling. A minimum of 4 inches is required in front of the central station computer to accommodate changing thermal printer paper.

OPERATIONAL CHARACTERISTICS

Computer

Pentium-III 500 MHz or faster

32 MB RAM

1 GB Hard Drive or larger

3.5-inch Floppy Drive

VGA card

2-inch Thermal Printer (optional)

Serial Mouse

101-key Keyboard

Monitor

15 or 19 inch diagonal screen

Touchscreen hardware installed

800 x 600 pixel resolution

256 colors

CHARACTERISTICS OF RADIO-LINK TRANSCEIVERS

Central Transceiver Transmitter

Frequency 902 to 928 MHz

RF Output Power +20 dBm (100 mW) minimum

RF Power Adj. >20 dB range

Specifications

Settling Time	<100 μ sec
Frequency Stability	$\pm 0.001\%$
Modulation Type	Direct FM, DDS Synthesized NRZ
Modulation Rate	62.5 kilobaud (nominal)
Antennas	Omni-directional
Spectrum Usage	Spread spectrum (IAW FCC Par. 15.247)
FCC	FCC Part 15, Section 101 - Class A with exceptions for intentional radiators covered by FCC Part 15, Section 247

Central Transceiver Receiver

Frequency	902 to 928 MHz
Frequency Spacing	1 kHz
Settling time	Less than 100 μ sec
Frequency Stability	$\pm 0.001\%$
Selectivity	180 kHz (3 dB) nominal 300 kHz (20 dB) nominal
Sensitivity	-80 dBm (minimum) in 180 kHz bandwidth for 10 dB SNR
Modulation Type	Direct FM, DDS Synthesized NRZ
Modulation Rate	133 kilobaud
Diversity	Full voting, 2 channels
Input impedance	2:1 VSWR maximum (50 ohm)
Host PC Interface	Memory-mapped, dual port RAM
Antennas	Omni-directional

Remote Transceiver Transmitter

Frequency	902 to 928 MHz
RF Output Power	+15 dBm nominal, ± 2.0 dB
RF Power Adj.	>20 dB range

Settling Time	<300 μ sec
Frequency Stability	$\pm 0.001\%$
Modulation Type	Direct FM, DDS Synthesized NRZ
Modulation Rate	133 kilobaud (nominal)
Frame Length	30 milliseconds
Data Rate	Instantaneous bandwidth variability
FCC	FCC Part 15, Section 101 - Class B with exceptions for intentional radiators covered by FCC Part 15, Section 247

Remote Transceiver Receiver

Frequency	902 to 928 MHz
Settling time	<300 μ sec
Frequency Stability	$\pm 0.001\%$
Selectivity	180 kHz (3 dB) nominal 300 kHz (20 dB) nominal
Sensitivity	-90 dBm (minimum) in 180 kHz bandwidth for 10 dB SNR
Spurious Rejection	50 dB nominal
Modulation Type	100 kHz deviation NRZ
Modulation Rate	133 kilobaud
Input impedance	2:1 VSWR maximum (50 ohm)

MINIMUM REQUIREMENTS FOR LASER PRINTER

The *Oxinet II* monitoring system supports printers that are both HPGL/2 and PCL5 compatible with a minimum of 2 megabytes of printer memory such as the Hewlett-Packard LaserJet models 4, 4SI, 4L, 5, 5SI, and 5L printers.

AGENCY REGULATORY NOTICES

The central station complies with the following environmental and performance testing and inspection requirements:

CSA 22.2 no. 125

UL 544

IEC 801.2-5 with FDA allowable exceptions

FCC part 15, Section 247 - Spread Spectrum

FCC part 15, Section 249 - Fixed Frequency

EN 50081-1

EN 55022/CISPR 11 Class A

This device complies with CSA 22.2 No. 950 and IEC 601-1-1.

COMPONENT AND SYSTEM LABELS

An identification label showing product part number, model, serial number and hardware level is affixed on the rear panel of the central station computer by the original manufacturer. This label facilitates product traceability through the manufacturer's product records system.

Another label shows CSA/NRTL/C certification that is applicable to the *Oxinet* II monitoring system as a whole. This certification is based on the Canadian Standard for Electromedical Equipment, C22.2, No. 125 and the Underwriters Laboratories Standard for Medical and Dental Equipment, UL544.

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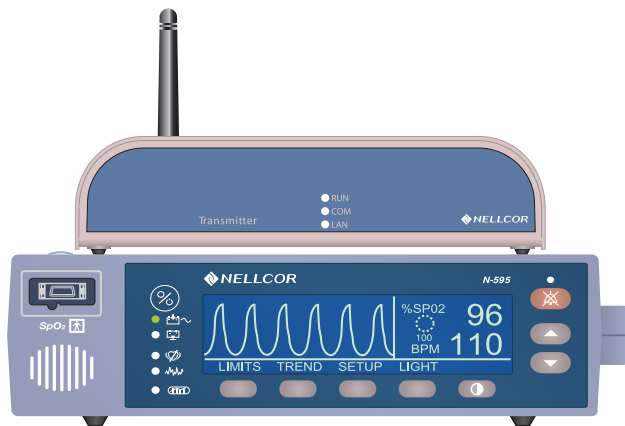
Rx ONLY

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EXHIBIT 7



Oxinet[®] III



SERVICE MANUAL

Nellcor Puritan Bennett Incorporated is an affiliate of Tyco Healthcare. Nellcor and Oxinet are trademarks of Nellcor Puritan Bennett Incorporated.

To obtain information about a warranty, if any, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative.

Purchase of this instrument confers no express or implied license under any Nellcor Puritan Bennett patent to use the instrument with any sensor that is not manufactured or licensed by Nellcor Puritan Bennett Incorporated.

Covered by one or more of the following U.S. Patents and foreign equivalents: 4,802,486; 4,869,692; 4,934,372; 5,078,136; 5,351,685; 5,485,847; 5,533,507; 5,577,500; 5,803,910; 5,865,736; 6,463,310; 6,708,049; Re.35, 122.

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Introduction

Warnings



Warnings are identified by the WARNING symbol shown above.

Warnings alert the user to potential, serious outcomes (death, injury, or adverse events) to the patient or user.



WARNING: The Oxinet[®] III system is not intended to be a substitute for clinical supervision. Patients on life-support equipment should be appropriately monitored by competent medical personnel and suitable monitoring devices.



WARNING: The Oxinet III system is a secondary alarm notification system. It is intended to supplement and not to replace any part of the hospital's device monitoring procedures (including procedures regarding bedside pulse oximeters and responding to bedside oximeter alarms). Do not rely on the Oxinet III system as the sole source of oximeter alarms.



WARNING: It is essential that the Central Station be visually and/or audibly monitored at all times to assure prompt response to alarms. Do not rely on the pagers as the sole source of Oxinet III alarms.



WARNING: Do not ignore medical device audible alarms. Alarms indicate conditions that require immediate attention.



WARNING: Do not use medical devices, parts, accessories, or options that are not for use with the Oxinet III system.



WARNING: Users are not notified when the pager is out of range of the transmitter.



WARNING: Explosion hazard. Do not use the Oxinet III system in the presence of flammable anesthetics or gases or oxygen-enriched environments.



WARNING: The Oxinet III transmitter is not defibrillator-proof. Although it may remain attached to a monitor that is attached to a patient during defibrillation or while an electrosurgical unit is in use, its transmission may be interrupted during defibrillator use.



WARNING: Do not use an Oxinet III transmitter, pager, or Central Station that appears to be damaged.



WARNING: Do not spray, pour, or spill any liquid on the Oxinet III, its accessories, connectors, switches, or openings in the chassis since this may damage the Oxinet III system. (The transmitter, pager, or any other system component must be removed from service if they ever become submerged in liquid.) To ensure accurate performance and prevent device failure, do not subject the Oxinet III to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

Cautions



Cautions are identified by the CAUTION symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of the Oxinet III system.



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



Caution: The Oxinet III software is intended for use with the following oximeters: the Nellcor N-395, N-550, N-595, N-560, and N-600.



Caution: The displayed data is limited to that provided by the medical device.



Caution: Refer to the operator's manuals for the specific pulse oximeter for oximeter warnings and cautions.



Caution: Oxinet III software is intended to run on computers that meet the minimum requirements set forth in the Specifications chapter of this manual. No applications other than those specified should be installed or executed on the application server.

Notes



Notes are identified by the **Note** symbol shown above.

Notes contain important information that may otherwise be overlooked or missed.

Manual Overview

This manual contains information for the Oxinet III system. All users should read this manual completely. More experienced users can use this manual as a reference.

The latest versions of this service manual and the operator's manual are available online, along with other Nellcor oximetry manuals, at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

System Overview

Intended Use

The Oxinet III system transmits data from the N-395, N-550, N-595, N-560, or N-600 pulse oximeter to the Central Station for patient monitoring, via a wired or wireless configuration. The Central Station displays all monitored rooms, relevant pulse oximeter data, and alarms.



WARNING: The Oxinet III system is a secondary alarm notification system. It is intended to supplement and not to replace any part of the hospital's device monitoring procedures (including procedures regarding bedside pulse oximeters and responding to bedside oximeter alarms). Do not rely on the Oxinet III system as the sole source of oximeter alarms.

The intended patient population is comprised of adult, pediatric, and neonatal patients. The intended environments of use are hospitals and hospital-type facilities. Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, and intensive and critical care areas within the hospital and hospital-type facilities, such as surgicenters, sub-acute centers, special nursing facilities, and sleep labs, outside of the hospital. The Oxinet III system is for use by prescription only.

Description

The Oxinet III software collects and distributes time-sensitive oximetry data via wired or local network wireless technology. Making use of the Intranet's security and connectivity standards, the Oxinet III software enables the review and surveillance of medical device settings and real-time patient data remotely, using a standard HTML compatible web browser.

The components that make up the wireless and wired systems are listed below.

Wireless Configuration:

- Pulse Oximeter (suitable for use within the patient environment)
- Transmitter (suitable for use within the patient environment)
- Access Point
- Router/Switch
- Central Station (application server)
- Oxinet III Operator's Manual
- Pager Transmitter (optional)
 - Pagers, at least two, if pager option installed

Wired Configuration:

- Pulse Oximeter (suitable for use within the patient environment)
- Communication Server
- Router/Switch
- Central Station (application server)
- Oxinet III Operator's Manual
- Pager Transmitter (optional)
 - Pagers, at least two, if pager option installed

Each of these systems is discussed in more detail in the following sections.

Wireless Configuration

In a wireless configuration (Figure 1), each Pulse Oximeter is connected to a Transmitter. Each Transmitter communicates wirelessly with an Access Point, which is connected through a Router/Switch to the Central Station (application server), where the patient's data may be monitored. The Central Station can be connected to an optional Pager Transmitter: if pagers are assigned to a patient, alarms are transmitted from the oximeter to the Central Station, then through the Pager Transmitter to the assigned pagers. *The range of operation from pager transmitter to pager is 150 feet with no intervening structures.*

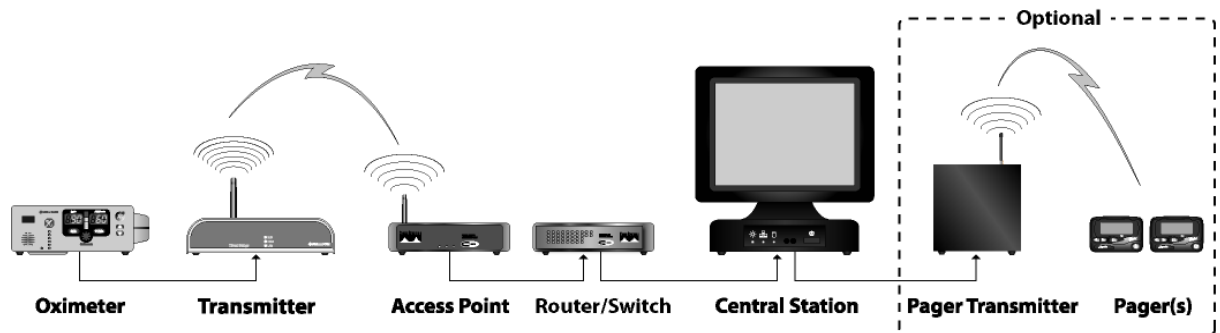


Figure 1: Wireless Configuration — with Optional Pager Transmitter

Wired Configuration

In a wired configuration (Figure 2), all pulse oximeters are connected to a Communication Server (generally, the pulse oximeters are connected to a port in the wall, which connects to the Communication Server housed in a data communications closet). The Communications Server is connected to a Router/Switch, which is connected to the Central Station (application server), where the patient's data may be monitored. The Central Station can be connected to an optional Pager Transmitter: if pagers are assigned to a patient, alarms are transmitted from the oximeter to the Central Station, then through the Pager Transmitter to the assigned pagers.

In either configuration, the Central Station (application server) is the computer running the Oxinet III software. The software displays all monitored rooms, relevant Pulse Oximeter data, and alarms.

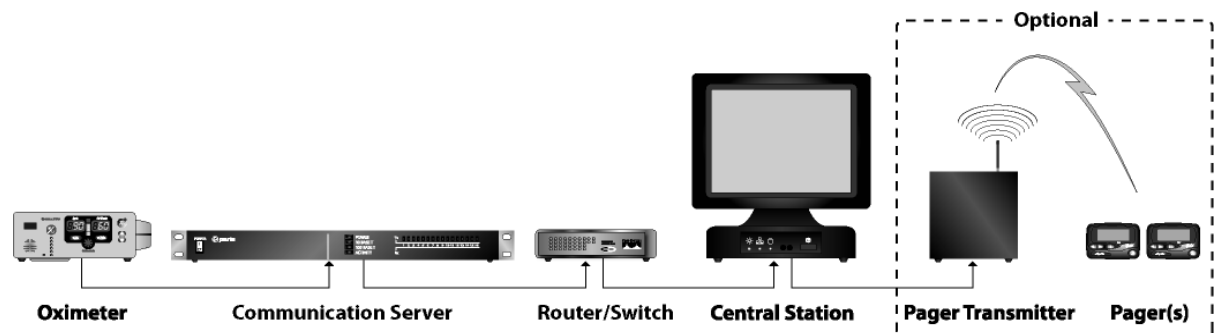


Figure 2: Wired Configuration — with Optional Pager Transmitter

Alarms

Alarms appear audibly and visually at the Central Station. If the optional paging system is used, an alarm text message is transmitted to a pager, displaying the room number, patient name, alarm message, SpO₂ value, and pulse rate at the time of the alarm.



Note: The Oxinet III software performs database maintenance automatically: the software temporarily closes the program, performs database file maintenance, and relaunches the program at 10:05 am every day. This maintenance procedure normally takes less than 45 seconds to run. ***During the brief period that database maintenance is in progress, the system does not process any incoming data — including alarms.***

Reports

The Oxinet III software allows up to 72 hours of monitored data to be stored, trended, and retrieved in a variety of printable reports. Reports can be run at any time or periodic snapshots of oximetry data can be scheduled at intervals selected by the clinician.

Pagers

Use of pagers with the Oxinet III system is optional, since patients are being continuously monitored at the Central Station. If you decide to assign pagers to a patient, you should assign both a primary and a secondary pager. The primary pager receives the alarm page within 10 seconds of the alarm. If no one responds to the alarm by either silencing the alarm at the oximeter or resolving the reason for the alarm, the system sends a notification to the secondary pager within 30 to 120 seconds of the primary page, depending on the settings for your Oxinet III system.



WARNING: It is essential that the Central Station be visually and/or audibly monitored at all times to assure prompt response to alarms. Do not rely on the pagers as the sole source of Oxinet III alarms. The Oxinet III system is a secondary alarm notification system. It is intended to supplement and not to replace any part of the hospital's device monitoring procedures (including procedures regarding bedside pulse oximeters and responding to bedside oximeter alarms).

Component Descriptions

Table 1: Wireless Configuration

Component	Description
Pulse Oximeter	The pulse oximeter monitors and processes patient data and sends this digital data to the transmitter via the oximeter's serial data port. The following Nellcor oximeters are supported: N-395, N-550, N-595, N-560, and N-600.
Transmitter	The transmitter converts serial data from the oximeter to Ethernet data and then transmits the data to the access point.
Access Point	The access point receives the wireless data from the transmitter and forwards it to the router/switch. A number of access points can be installed together to create a Wireless Local Area Network (WLAN), which can cover a single care unit, a single floor, or multiple floors. The number of access points required to create the WLAN is determined by the size of the area to be monitored. Because every building is unique, access point placement must be determined by trained personnel before the Oxinet III installation. It is not recommended that an access point be moved after installation, since the wireless coverage area will be affected.
Router/Switch	The router/switch receives patient data from the access point via the Ethernet network connection (or through the Cat5 Patch cable) then forwards the data to the Central Station (application server).
Central Station (application server)	The Central Station (application server), the computer running the Oxinet III software, displays all monitored rooms/beds, relevant pulse oximeter data, and alarms. Oximetry data is received from the connected router/switch and, if the optional paging feature is used, sends the alarm data to the pager transmitter for transmission to the assigned pagers.
Pager Transmitter (optional)	The pager transmitter receives the alarm data through the serial RS-232 port of the Central Station and sends a text message to the assigned pager(s) that includes: the room number, patient name, alarm message, time and date.

Table 2: Wired Configuration

Component	Description
Pusle Oximeter	The pulse oximeter monitors and processes patient data and sends this digital data to the Communication Server via hardwire connection to the oximeter's serial data port. The following Nellcor oximeters are supported: N-395, N-550, N-595, N-560, and N-600.
Communication Server	The communication server is hard-wired to each bedside location and converts digital serial data from the serial port of the pulse oximeter to Ethernet data, then forwards that Ethernet data to the Ethernet router/switch.
Router/Switch	The router/switch receives patient data from the communication server via the Ethernet network (or through the Cat5 Patch cable) and then forwards the data to the Central Station (application server).

Table 2: Wired Configuration (Continued)

Component	Description
Central Station (application server)	The Central Station (application server), the computer running the Oxinet III software, displays all monitored rooms/beds, relevant pulse oximeter data, and alarms. Oximetry data is received from the connected router/switch and, if the optional paging feature is used, sends the alarm data to the pager transmitter for transmission to the assigned pagers.
Pager Transmitter (optional)	The pager transmitter receives the alarm data through the serial RS-232 port of the Central Station and sends a text message to the assigned pager(s) that includes: the room number, patient name, alarm message, time and date.

Installation

Power and Space Requirements



Caution: Oxinet III system power cords should only be connected to properly grounded 120V AC, 60 Hz outlets.

When installing the components, leave space beyond the dimensions listed in Table 3 to accommodate cables and to provide adequate ventilation to prevent overheating.

Table 3: Component Dimensions

Component	Dimensions (height x width x depth)
Transmitter	6.93" W x 1.9" H x 4.26" D (176 mm W x 48 mm H x 107 mm D)
Access Point	7.75" W x 1.25" H x 5.5" D (197 mm W x 32 mm H x 140 mm D)
Communication Server	16.93" W x 1.77" H x 9.01" D (430 mm W x 45 mm H x 229 mm D)
Router/Switch	7.32" W x 1.89" H x 6.06" D (184 mm W x 46 mm H x 154 mm D)
Central Station	14.4" W x 12.7" H x 13.7" D (367 mm W x 323 mm H x 348 mm D) wall mountable
Pager Transmitter	8.5" W x 8.5" H x 2" D (216 mm W x 216 mm H x 51 mm D) wall mountable

Place the optional pager transmitter in a location where it is not close to large metal objects such as tall metal filing cabinets or metal desks, which tend to interfere with radio frequency signals. In addition, the pager transmitter should be placed at least 3 feet away from other electronic equipment such as computers, radios, or PA systems to minimize interference with those systems.



Note: Typical symptoms of interference include flickering screens on the Central Station or a computer monitor, or hissing/popping sounds coming from speakers. If either of these symptoms occur, increase the distance between the pager transmitter and the device exhibiting the symptoms.

Installation

The initial setup and installation of the Oxinet III system at a designated site should only be performed by trained Nellcor personnel or authorized representatives. The installation information provided in this manual can be used to reconnect the Oxinet III system if a component needs to be replaced.

Wired Configuration

The following Nellcor oximeters are supported in the Oxinet III system:

- N-395
- N-550
- N-595
- N-560
- N-600

The Oximeter data output port must be configured as follows:

- communication protocol — ASCII
- baud rate — 9600

Refer to the service manual for the Oximeter for details on Oximeter settings.

Connect the Oximeter to the Communication Server

- 1 Plug a DB15M/RJ-45 Cat5 Adapter connector into the data port of each Oximeter (patient room/bed) as shown in Figure 3.
- 2 Connect a AC power cord to the power input jack on the back of each Oximeter and plug the other end into AC power outlet.
- 3 Connect a Cat5 Patch cable from the DB15M/RJ-45 connector of each Oximeter to an available serial port on the back of the Communication Server and take note of the room sequence versus the communication serial port number (Figure 3).

Connect the Communication Server to the Router/Switch

- 1 Connect the Cat5 Patch cable from the 10/100 Base-T network port on the Communication Server to any available numbered RJ-45 LAN port on the Router/Switch as shown in Figure 3 (**DO NOT use the port labeled “WAN”**).
- 2 Connect a AC power cord to the power input jack on the back of the Communication Server and plug the other end into one of the battery backed-up AC power outlets of the UPS.
- 3 Connect the DC barrel connector end of the DC Adapter Power cable to the round DC jack on the back of the Router/Switch and plug the AC end into one of the battery backed-up AC power outlets of the UPS.

Connect the Router/Switch to the Central Station

- 1 Remove the back panel on the base of the Central Station to gain access to the ports (Figure 3).
- 2 Connect a Cat5 Patch cable from any of the numbered RJ-45 LAN ports on the back of the Router/Switch to the network port in the back of the base of the Central Station (Figure 3).

Connect the Central Station to the Pager Transmitter (Optional)

This procedure needs to be perform only if your system includes the optional Pager Transmitter.

- 1 Remove the back panel on the base of the Central Station to gain access to the ports (Figure 3).
- 2 Connect an AC power cord to the power input jack on the back of the base of the Central Station and plug the other end into one of the battery backed-up AC power outlets of the UPS (Figure 3)



Caution: To avoid damaging the Pager Transmitter, connect its antenna before connecting power to the Pager Transmitter.

- 3 Connect the antenna for the Pager Transmitter to the BNC connector on the Pager Transmitter (Figure 3).
- 4 Connect one end of the two-ended RS-232 serial cable to the **COM1** serial port of the Central Station, and connect the other end to the **RS232C Interface** serial port on the left side of the Pager Transmitter (Figure 3).
- 5 Connect the DC power cable into the **12V DC** power port of the Pager Transmitter and plug the AC cord into the AC power outlet (Figure 3).
- 6 Connect the mouse and keyboard to the Central Station (Figure 3).

Connect the Printer to the Central Station

You need to connect a Printer to the Central Station in order to print Oxinet III reports.

- 1 Remove the back panel on the base of the Central Station to gain access to the ports (Figure 3).
- 2 Connect the printer cable from the printer to the parallel port connector on the back of the base of the Central Station (Figure 3); if you are using a USB printer, connect the USB cable to the USB port on the back of the Central Station base.

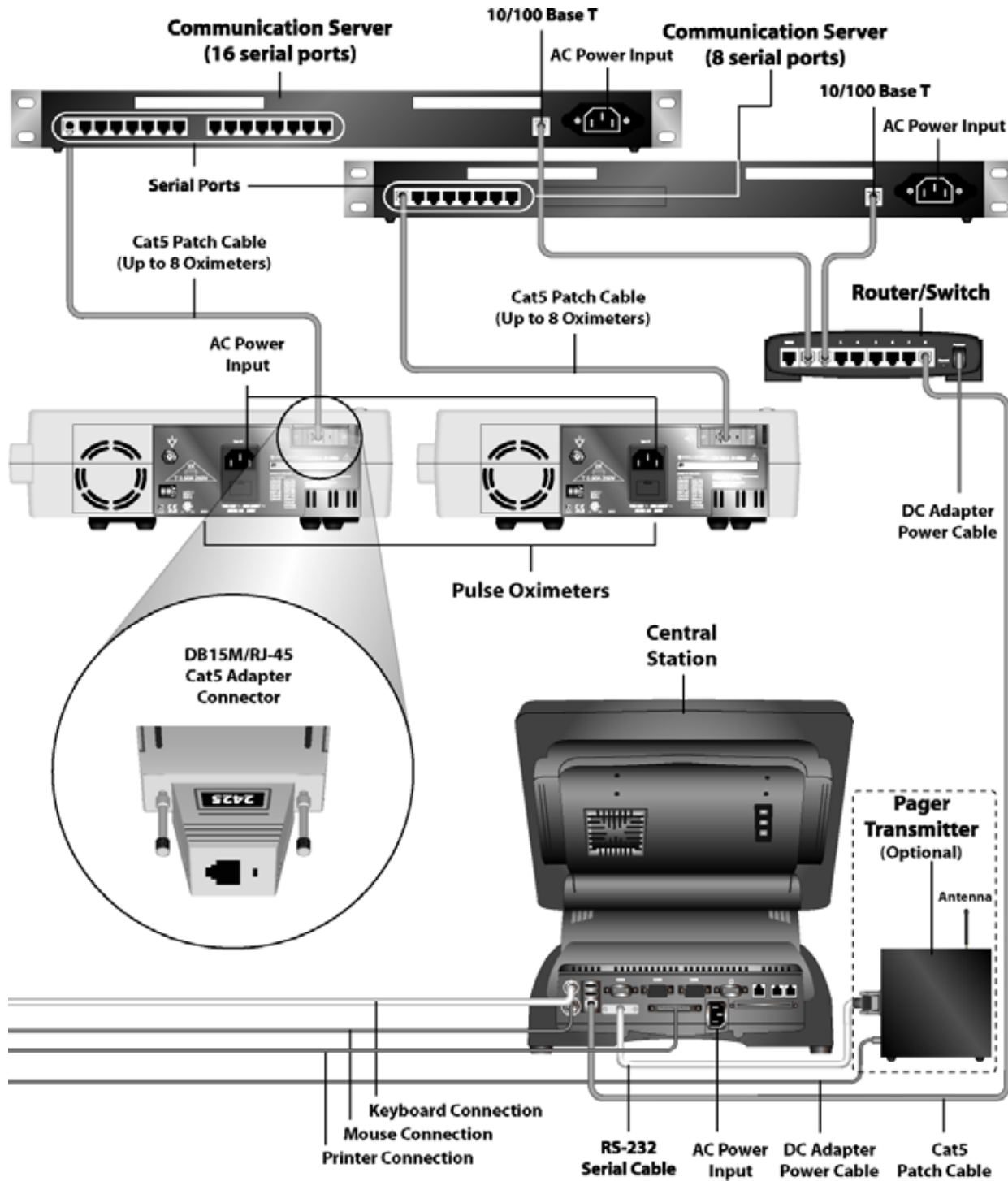


Figure 3: Wired Configuration System Connection

Wireless Configuration

Connect the Oximeter to the Transmitter

The following Nellcor oximeters are supported in the Oxinet III system:

- N-395
- N-550
- N-595
- N-560
- N-600

The oximeter data output port must be configured as follows:

- communication protocol — ASCII
- baud rate — 9600

Refer to the service manual for the Oximeter for details on Oximeter settings.

- 1 Place the Transmitter near or on top of the Oximeter (Figure 4).
- 2 Connect the Oximeter to the Transmitter using the transmitter's RS-232 cable (Figure 4).
- 3 Connect one end of the AC Y-cord to each unit (Oximeter and Transmitter) and plug the other end into the AC outlet (Figure 4).

Connect the Access Point to the Router/Switch

- 1 Install a Cat5 cable from the RJ45 jack on the back of the Access Point to any of the numbered RJ-45 LAN ports on the back of the Router/Switch (Figure 4).
- 2 Connect the Access Point Antenna to the Primary Antenna Connector on the back of the Access Point (Figure 4).
- 3 Connect DC barrel connector end of the DC Adapter Power cable to the round DC jack on the back of the Router/Switch and plug the AC plug end into an AC outlet (Figure 4).
- 4 Connect DC power to the Access Point by performing either the *Single Access Point Power Supply Connection* procedure or the *Multiple Access Points Distributed Power Supply Connection* procedure.
 - a. **Single Access Point Power Supply Connection** — This option can be used if a single Access Point is to be installed in a location (such as a bookcase or tall shelf) where an AC power outlet is available.
 - Plug the DC barrel connector end of the DC Adapter Power cable into the round power jack on the access point and plug the AC power cord into an AC outlet (Figure 4).

- b. Multiple Access Points Distributed Power Supply Connection** — This option can distribute 15V DC power to as many as six access points, concurrently. The distributed power supply is useful when multiple access points are used to cover larger areas or when there is no AC outlet near the access point (such as when an access point is installed in a ceiling plenum).

Perform the following steps to connect DC power to multiple access points:

1. Run a cable between the distributed power supply and each Access Point separately. Since a data cable also has to be run to each Access Point, a cable contractor can pull the two cables at the same time.

The cable type required for the distributed power supply is a stranded 18 AWG, STP (shielded twisted pair) with an overall foil shield with a rating appropriate for the application (plenum rated, for example). Follow local, state, and national regulations regarding cabling. An electrician or licensed contractor should be consulted. The power cable must be terminated with a special barrel connector at the access point. The white striped connector is positive.

2. Plug the barrel connector into the round power jack on the Access Point.
3. Connect the opposite end of the power cable to terminal blocks on the power distribution panel of the distributed power supply. When terminating the ends of the power cable, observe polarity.
4. Plug the AC power cord of the distributed power supply into an AC outlet.
5. Repeat the process for each Access Point.



Note: When multiple access points are combined to cover large areas, it might be necessary to use multiple switches and multiple distributed power supplies.

Connect the Router/Switch to the Central Station

- 1 Remove the back panel on the base of the Central Station to gain access to the ports.
- 2 Connect a Cat5 cable from any of the numbered RJ-45 LAN ports on the back of the router/switch to the network port in the back of the base of the Central Station (Figure 4).
- 3 Connect the Central Station's antenna as shown in Figure 4.
- 4 Connect power cord from the power jack on the back of the base of the Central Station to one of the battery backed-up AC power outlets of the UPS.
- 5 Connect the mouse and keyboard to the Central Station (Figure 4).

- 6 Connect DC barrel connector end of the DC Adapter Power cable to the round DC jack on the back of the Router/Switch and plug the AC plug end into an AC outlet (Figure 4).

Connect the Central Station to the Pager Transmitter (Optional)

This procedure needs to be perform only if your system includes the optional Pager Transmitter.

- 1 Remove the back panel on the base of the Central Station to gain access to the ports



Caution: To avoid damaging the Pager Transmitter, connect its antenna before connecting power to the Pager Transmitter.

- 2 Connect the antenna for the Pager Transmitter to the BNC connector on the Pager Transmitter (Figure 4).
- 3 Connect the Central Station's antenna as shown in Figure 3.
- 4 Connect one end of the two-ended RS-232 serial cable to the **COM1** serial port of the Central Station, and connect the other end to the **RS232C Interface** serial port on the left side of the Pager Transmitter (Figure 4).
- 5 Connect the DC power cable into the **12V DC** power port of the Pager Transmitter and plug the AC cord into the AC power outlet (Figure 4).
- 6 Connect the Central Station to an AC power outlet, and connect the mouse and keyboard to the Central Station (Figure 4).

Connect the Printer to the Central Station

You need to connect a printer to the Central station in order to print Oxinet III reports.

- 1 Connect the printer cable from the printer to the parallel port connector on the back of the base of the Central Station (Figure 4).
- 2 If you are using a USB printer, connect the USB cable to the USB port on the back of the Central Station base.

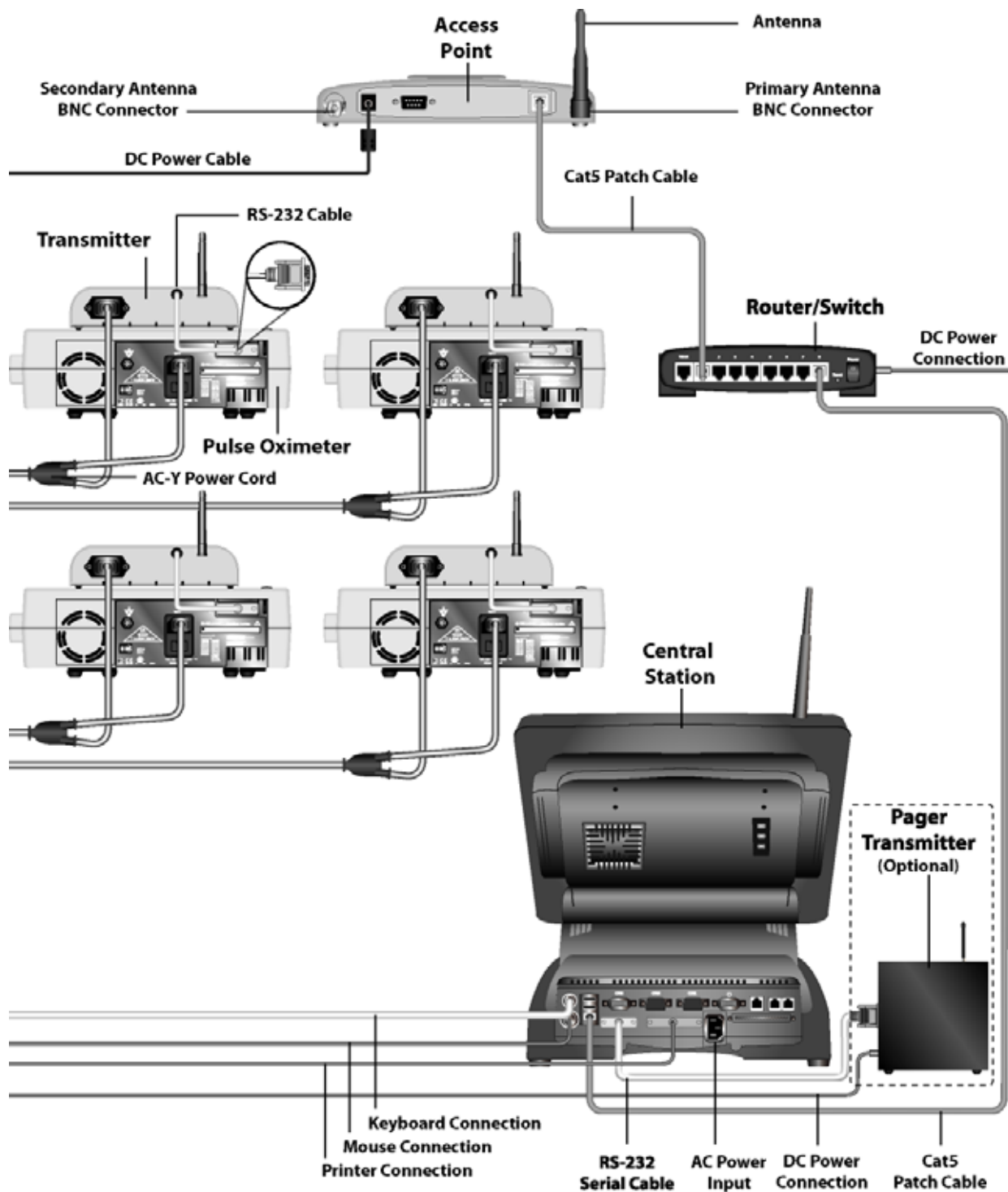


Figure 4: Wireless Configuration System Connection

Administrative Functions

Central Station

The Central Station performs various Administrative functions for the Oxinet III system.



Caution: The procedures described in this chapter must be performed by qualified service personnel.

All but one of the Administrative functions are password-protected to prevent access by unauthorized personnel. The password is provided in this chapter.

There are two ways to gain access to the Administrative functions, either via an externally connected keyboard or by using the on screen “touchscreen” keyboard.

You may also want to connect a mouse instead of using the touchscreen capability. To connect the mouse and the keyboard, you must remove the back panel on the base of the Central Station to get access to the ports (see Figure 3 or Figure 4 in the Installation chapter of this manual).

Once the mouse and the keyboard are connected, use the **On/Off** button to restart the Central Station (Figure 5).



Figure 5: Central Station - On/Off Button

Function Keys Explained

The keyboard's function keys must be used to access the Administrative functions of the Oxinet III Central Station. Table 4 lists and describes each of the function keys.

Table 4: Function Keys Explained

Key	Description
F5	Allows you to refresh screen.
F7	Allows you to align the touchscreen.
F8	Allows you to adjust the volume.
F9	Allows you to backup the current system configuration or to restore the most current backed-up version of the system configuration.
F10	Allows you to change the various alarm settings, add/delete pagers, modify the room list, and schedule snapshots.
F11	Allows you to manually initiate database maintenance.

Refreshing the Screen (F5)

Refreshing the screen enables you to restart the current screen if there is a problem with the Central Station. For example, you may want to use the refresh function as the first step when troubleshooting error messages such as Network Communication Error or Pulse Oximeter Communication Error, if the operational status of the Central Station is suspect, or when troubleshooting system interference problems. This is the only Administrative function that is not password-protected; simply press the **F5** key on the keyboard to refresh the screen. *Refresh can also be performed by touching the Oxinet III logo on the lower tool bar.*

Aligning the Touchscreen (F7)

Alignment of the touchscreen is necessary if you notice the cursor is not lined up with your finger when using the touchscreen. This function is password-protected.

- 1 Press the **F7** key on the keyboard.

The uShield dialog box appears (Figure 6).

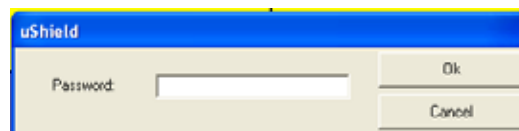


Figure 6: uShield Dialog Box

- 2 Type the Administrative function password, **1234**, then press or click the **Ok** button.

The *Elo Touchscreen Properties* dialog box opens (Figure 7).



Figure 7: Elo Touchscreen Properties Dialog Box

- 3 Press or click the **Align** button.

The system will guide you through the alignment process. When complete, press or click the **OK** button on the *Elo Touchscreen Properties* dialog box to close this function and return to the **Main Display** screen.

Adjusting Volume (F8)

This password-protected function enables you to control the Central Station volume.

- 1 Press the **F8** key on the keyboard.

The uShield dialog box appears (Figure 6).

- 2 Type the Administrative function password, **1234**, then press or click the **Ok** button.
- 3 The *Volume Control* dialog box appears (Figure 8).

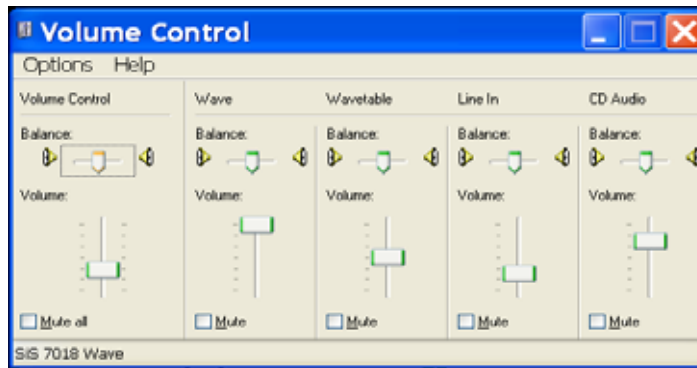


Figure 8: Volume Control Dialog Box

- 4 Make the following adjustments as desired:



Caution: The Oxinet III Central Station should NOT be muted.

- If the Volume Control's *Mute all* check box is selected, the volume is muted (turned off); clear the check box by clicking it to un-mute (turn-on) the volume.
- Raise and lower the volume by clicking and dragging the Volume slider in the *Volume Control* section — drag it up to raise the volume and down to lower the volume.
- When you have completed the volume adjustments, press or click the **X** in the upper right corner of the *Volume Control* dialog box to close this function and return to the **Main Display** screen.

Using Backup/Restore (F9)

Use this password-protected function to back up the current system configuration or to restore the most current backed-up version of the system configuration. A USB Memory Device is needed to perform this function — this accessory is included when the system is installed.

Backing up the Current System Configuration

- 1 Press the **F9** key on the keyboard.

The *Oxinet Backup Wizard* opens (Figure 9). The wizard will guide you through the backup process.



Note: Pressing (or clicking) the **Cancel** button enables you to cancel this action and close this function.



Figure 9: Backup/Restore Wizard

- 2 Type the Administrative function password, **1234**, then press or click the **Next** button.

The *Select an action* screen appears (Figure 10).

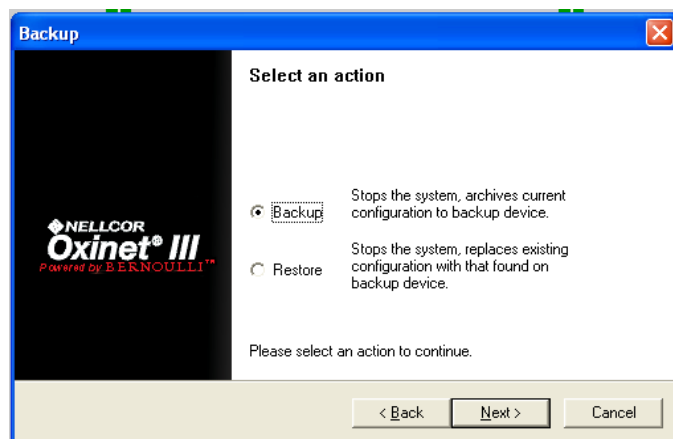


Figure 10: Backup/Restore Function — Select an Action

The system determines if the USB Memory Device is installed. If the device is installed, the **Backup Device Detected** message appears. If the device is not installed, the **No Backup Device Detected** message appears.



Note: Pressing (or clicking) the **Cancel** button enables you to cancel this action and close this function.



Figure 11: Backup Function

- 3 Press or click the **Next** button.

The system begins the backup process and displays the message: **Backup in Progress** (Figure 12). The desktop outside the Backup screen will be black.

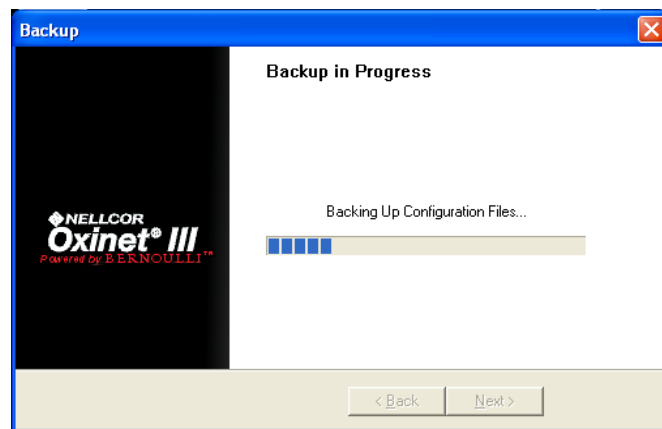


Figure 12: Backup in Progress

- 4 When the backup process is complete, the word **Done** appears (Figure 13).

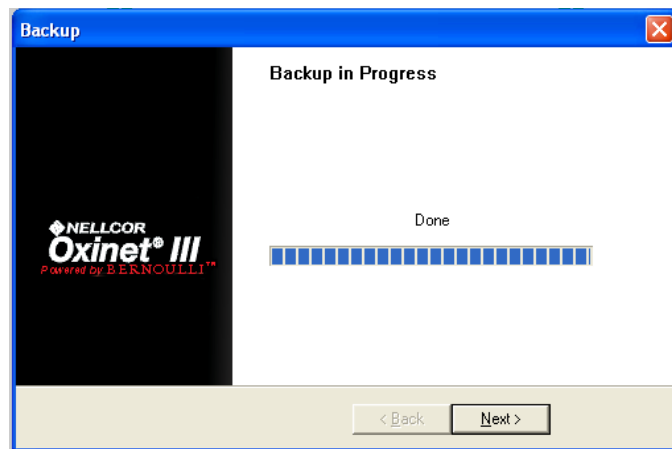


Figure 13: Backup in Progress — Done

- 5 Press or click the **Next** button.

The final message, **Backup Completed**, is displayed (Figure 14). Remove the USB Memory Device containing your saved version and store it in a secure location.

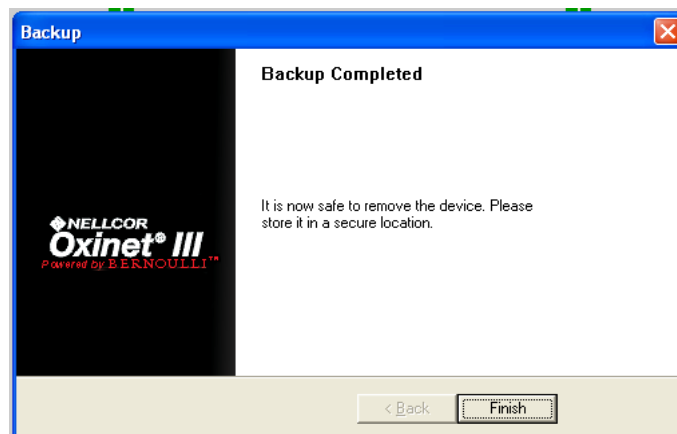


Figure 14: Backup Completed

- 6 Click the **Finish** button to close this function.

Restoring the Most Current Backed-up Version

Make sure the USB Memory Device, containing the most current backed-up version, is in place.

- 1 Press the **F9** key on the keyboard.

The *Oxinet Backup Wizard* opens (Figure 15). The wizard will guide you through the restore process.



Note: Pressing (or clicking) the **Cancel** button enables you to cancel this action and close this function.



Figure 15: Backup/Restore Wizard

- 2 Type the Administrative function password, **1234**, then press or click the **Next** button.

The *Select an action* screen appears (Figure 16).



Figure 16: Backup/Restore Function — Select an Action

- 3 Select the **Restore** option (Figure 16), then press or click the **Next** button.



Note: Pressing (or clicking) the **Back** button at any point in the Wizard enables you to return to the prior Wizard screen.

The system determines if the USB Memory Device is installed. If the device is installed, the **Restore Device Detected** message appears. If the device is not installed, the **No Backup Device Detected** message appears.

- 4 Press or click the **Next** button.



Figure 17: Restore Function

- 5 If you have more than one version backed up, the system asks you to select the version you want to restore; the most recent version will be the current selection. Press or click the drop-down arrow to view and select another saved version (Figure 18).

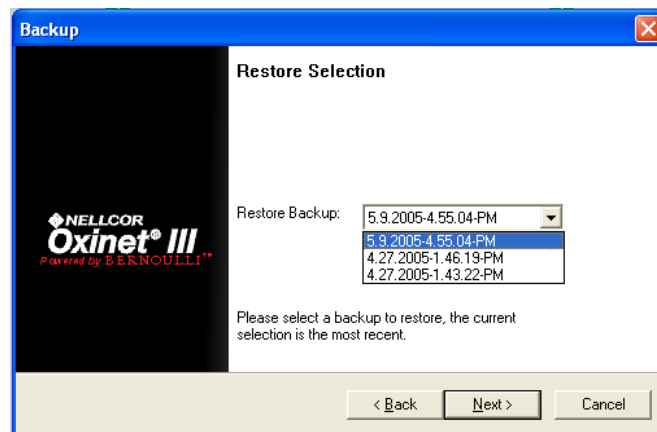


Figure 18: Restore Function —Select a Version

- 6 Press or click the **Next** button.
- 7 You will then be asked to confirm your version selection (Figure 19). Press or click the **Next** button to continue. Or, if you have selected the wrong version, click the **Back** button to return to the prior screen.

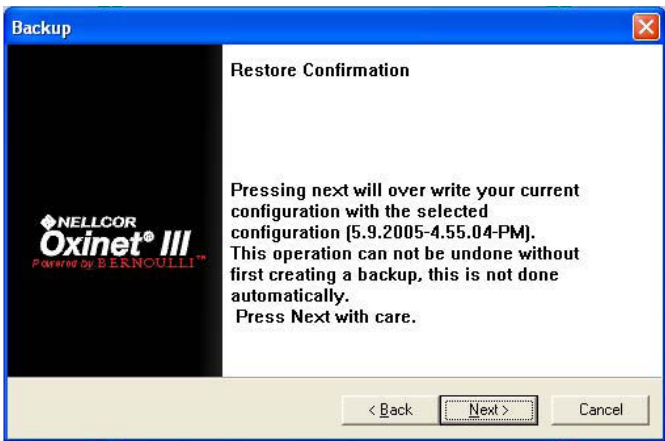


Figure 19: Restore Function — Confirm the Version

- 8 The system begins the backup process and displays the message: **Restore in Progress** (Figure 20).

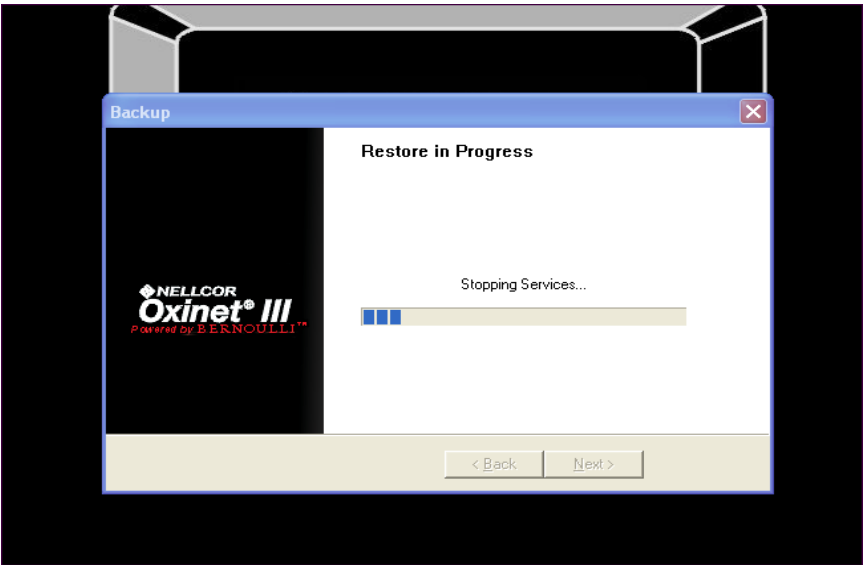


Figure 20: Restore in Progress

When the backup process is complete, the word **Done** appears (Figure 21).

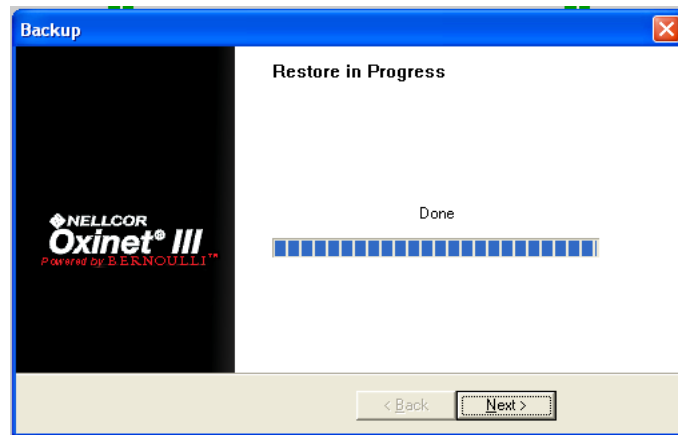


Figure 21: Restore in Progress - Done

- 9 Press or click the **Next** button.

The final message, **Restore Completed**, is displayed (Figure 22). Remove the USB Memory Device and store it in a secure location.



Figure 22: Restore Completed

- 10 Click the **Finish** button to close this function.

Oxinet Control Panel (F10)

- 1 Press the **F10** key on the keyboard.

The uShield dialog box appears (Figure 6).

- 2 Type the Administrative function password, **1234**, then press or click the **Ok** button.

The *Oxinet Control Panel* opens (Figure 23).



Figure 23: Oxinet Control Panel

The *Oxinet Control Panel* menus enable you to:

- Change the various alarm settings
- Add/delete pagers
- Modify the room list
- Schedule snapshots

There are four tabs at the top of the *Oxinet Control Panel* screen that identify each menu: **Alarms**, **Pagers**, **Rooms**, and **Schedule Snapshots**. To see a menu, press (or click) the corresponding tab.

Alarms Menu

The **Alarms** menu (Figure 24) is the first screen that appears when the *Oxinet Control Panel* opens.

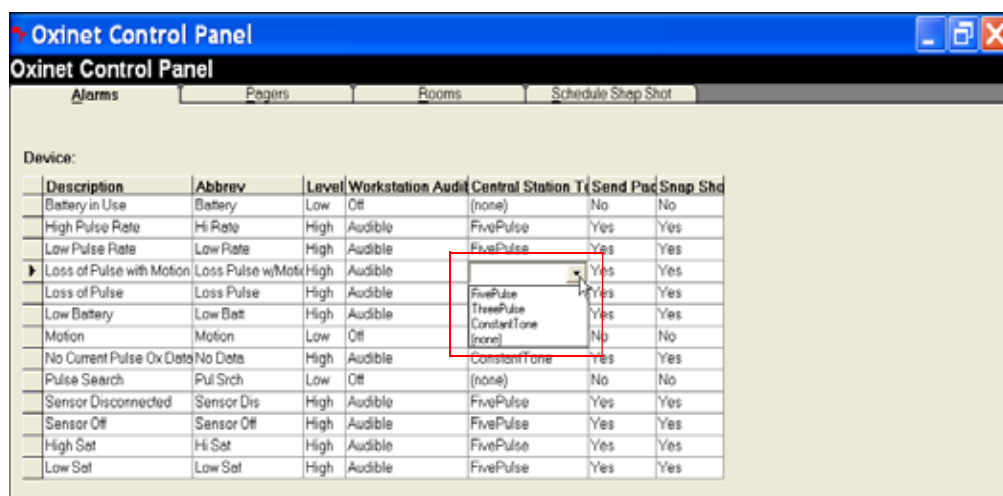


Figure 24: Alarms Menu

The first three columns contain alarm information (description, abbreviation, and level).

- 1 To change settings in the *Workstation Audible*, *Central Station Tone*, *Send Page*, or *Snapshot* columns, press (or click) within the cell for the setting you want to change.

A drop-down arrow appears (Figure 24).

- 2 Press (or click) the arrow and the list of options appears as shown in Figure 24.
- 3 Press (or click) the option to select it.

The change is made.

Table 5 lists and describes the alarm settings in the **Alarm** menu.

Table 5: Alarms Settings

Description	This is the message that appears on the Central Station when the alarm occurs (can be edited by a Nellcor Service technician only).
Abbrev	If pagers are assigned to a patient and the Yes option in the <i>Send Page</i> column is selected, this is the pager message that will be sent to the pager (can be edited by a Nellcor Service technician only).
Level	The settings in this column determines the priority level of an alarm: Low or High (can be edited by a Nellcor Service technician only).
Workstation Audible	The settings in this column determine if an audible alarm sounds on the Central Station when this alarm occurs: Audible or Off . Default setting is Audible .
Central Station Tone	The settings in this column determine the audible tone for the alarm: FivePulse , ThreePulse , Constant Tone , or (none) .
Send Page	The settings in this column determine whether or not this alarm will trigger an alarm page, if pagers are assigned to the patient: Yes or No .
Snapshot	The settings in this column determine if a snapshot will automatically be taken when this alarm occurs: Yes or No .

Pagers Menu

To Set Interval Between Initial Page to Primary Pager and Page to Secondary Pager:

- 1 Press (or click) the **Pagers** tab to open the **Pagers** menu as shown in Figure 25.

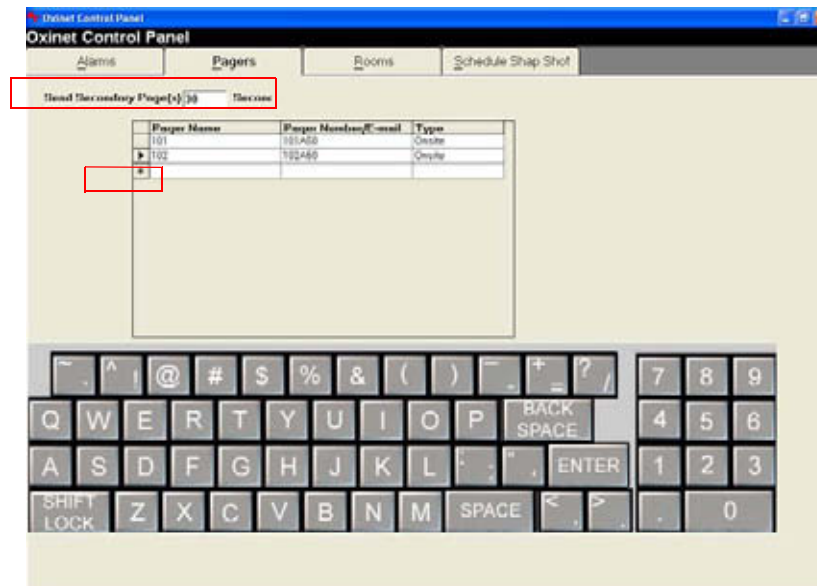


Figure 25: Pagers Menu — Initial

- 2 Use the *Send Secondary Page(s)* field to set the interval (in seconds) between the initial page to the primary pager and the page to the secondary pager(s), if pagers are assigned to the patient. For example, if you type **30** (Figure 25), the secondary pager notification will occur 30 seconds after the initial page occurs (if no one responds to the initial alarm page to either silence the alarm at the oximeter or resolve the reason for the alarm).

To Add a Pager:

- 1 Press (or click) the starred (*) cell (Figure 25) in the *Pager Name* column.

This inserts the cursor so you can type the pager name or number. Backspace to delete the word **New** (Figure 26).

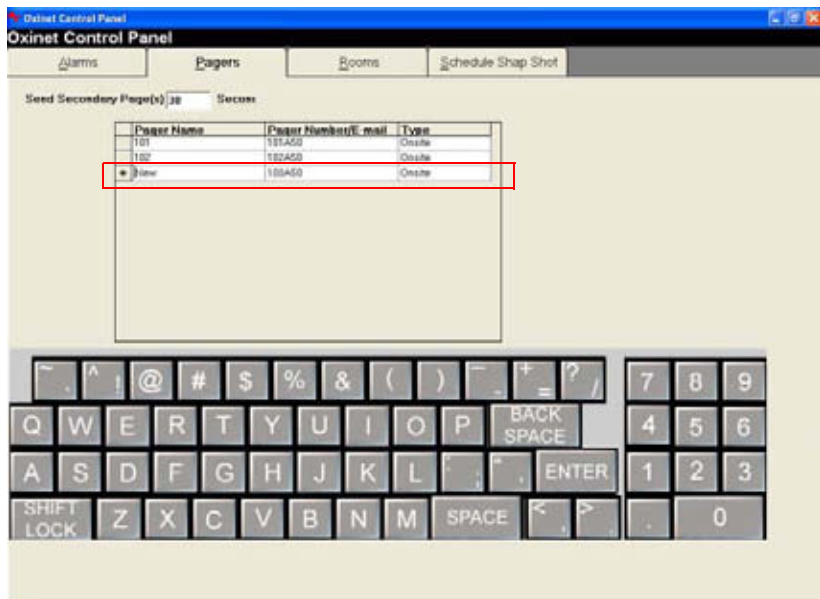


Figure 26: Pagers Menu — Adding Pager

- 2 Press (or click) the cell in the *Pager Name* column and type the pager number, for example **103** (Figure 27).

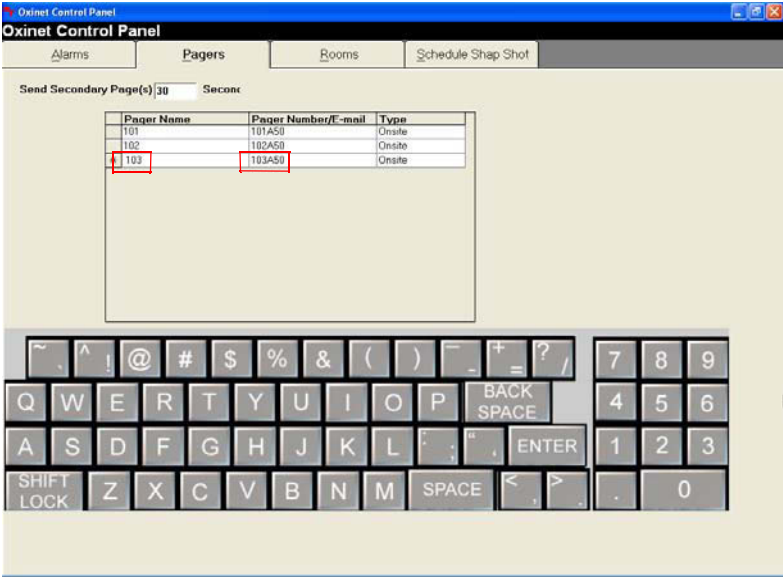


Figure 27: Pagers Menu — Entering Pager Name

3A Press (or click) the cell in the *Pager Number/E-mail* column and type the pager name and number, for example **103A50** (Figure 27) — the pager number is indicated on the back of the pager (in this example the pager number is 103).

OR

3B If the Oxinet III system is connected to a SMTP e-mail system on the hospital’s intranet and the Oxinet III system is connected to that intranet, you can type an e-mail address instead, then change the *Type* to **E-Mail** as shown in Figure 28.

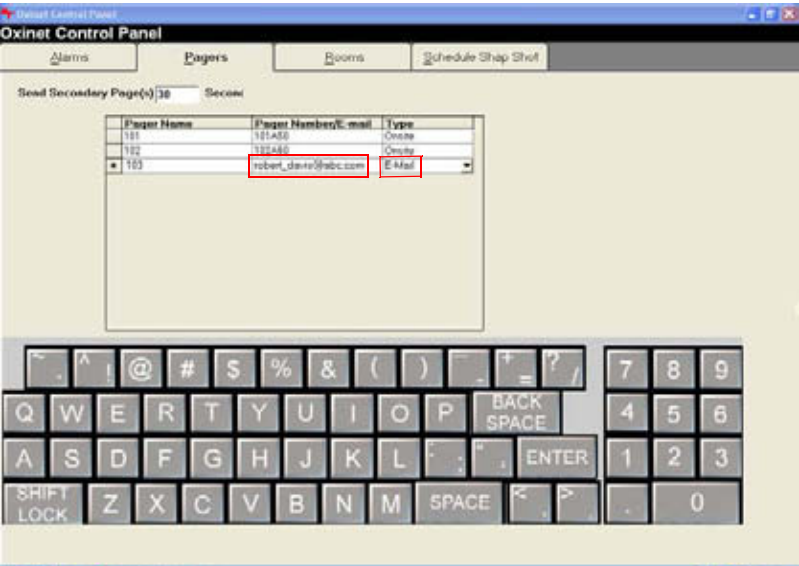


Figure 28: Pagers Menu — Entering Pager E-mail

To Edit a Pager:

Press (or click) the cell containing the information you want to modify, then make the change.

To Delete a Pager:

Press (or click) the area to the left of the row to highlight the row to be deleted, then press the **Delete** key on the keyboard.

Rooms Menu



Caution: Do not make changes to the room list while patients are being monitored — you must first discharge all patients from the Oxinet III system, then make any necessary changes to the list.

The *Unit* column enables you to group rooms/beds in categories that make sense for your facility. If you have multiple Units in the system, buttons representing each of those Units will appear at the top of the **Monitor** screen, so you can switch the **Monitor** view from one Unit to another. Figure 29 shows only one Unit, the **Step Down** Unit.

The *RoomSeq* field determines the order in which the rooms will be displayed on the **Available Room List** and the **Monitor** screens.

The **Tech Page** button is reserved for use by Nellcor Service technicians to clear room assignments in the event of a problem and is password-protected.

RoomId	Unit	RoomSeq
1	Step Down	1
2	Step Down	2
3	Step Down	3
4	Step Down	4
5	Step Down	5
6	Step Down	6
7	Step Down	7
8	Step Down	8
9	Step Down	9
10	Step Down	10
11	Step Down	11
12	Step Down	12
13	Step Down	13
14	Step Down	14
15	Step Down	15
16	Step Down	16
17	Step Down	17
18	Step Down	18
19	Step Down	19
20	Step Down	20

Figure 29: Rooms Menu

Schedule Snapshot Menu

Use the Schedule Snapshot menu to set the times for scheduled snapshots to occur (refer to the Running Reports chapter of the operator's manual for more information about Snapshots). Press (or click) the check box next to the desired time to select or clear it. For example, in Figure 30, snapshots will be taken for all patients in the Oxinet III system at midnight, at noon, at 4 am and 4 pm, and at 8 am and 8 pm.

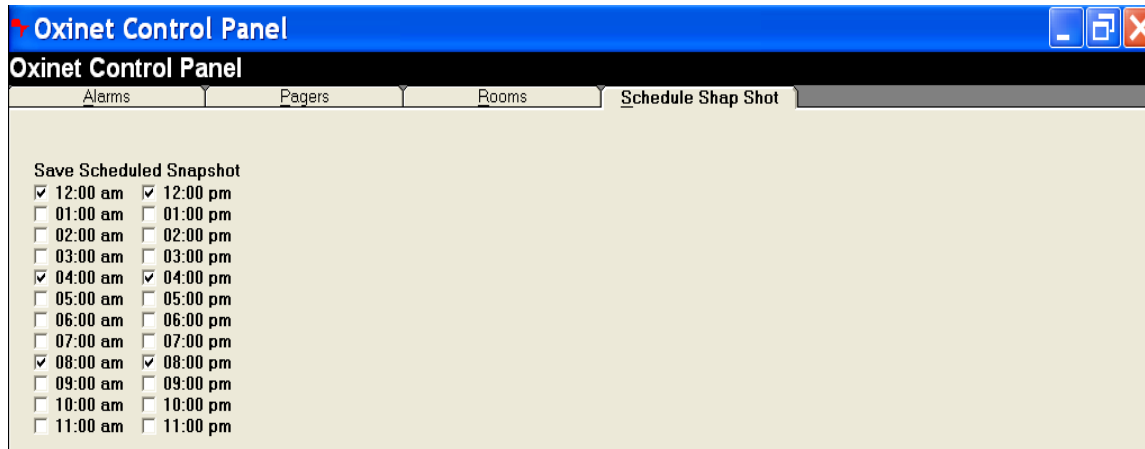


Figure 30: Schedule Snapshot Screen

Maintenance (F11)



Note: The Oxinet III software performs database maintenance automatically. The software temporarily closes the program, performs database file maintenance, and relaunches the program at 10:05 am every day. This maintenance procedure normally takes less than 45 seconds to run. ***During this brief period, the system does not process any incoming data, including alarms.*** To manually initiate the database maintenance process, perform the following procedure.

To Manually Initiate Database Maintenance

Use the **F11** function to *manually initiate database maintenance*. This function is password-protected.

- 1 Press the **F11** key on the keyboard.

The uShield dialog box appears (Figure 6).

- 2 Type the Administrative function password, **1234**, then press or click the **Ok** button.

When maintenance begins, the ***Please wait..Maintenance is running. This should take about 5 minutes to complete*** message appears. When maintenance is complete, the system returns you to the **Monitor** screen.

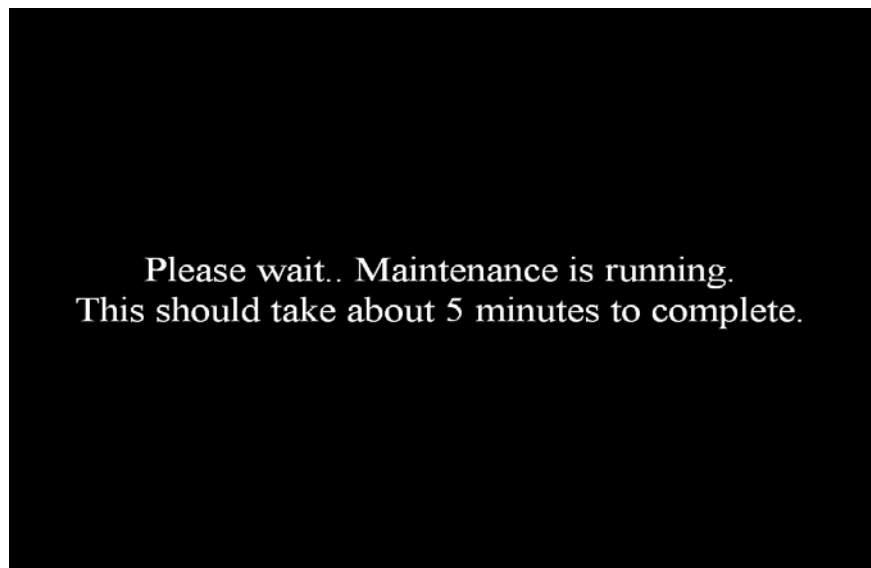


Figure 31: Database Maintenance

Maintenance

Service

If service is needed for any of the Oxinet III system components, contact qualified service personnel or your local Nellcor representative.

The Pager requires periodic replacement of the battery. Refer to the operator's manual for battery replacement instructions. The latest version of the operator's manual is available online at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html



Note: The Oxinet III software performs database maintenance automatically. The software temporarily closes the program, performs database file maintenance, and relaunches the program at 10:05 am every day. This maintenance procedure normally takes less than 45 seconds to run. ***During this brief period, the system does not process any incoming data, including alarms.*** To manually initiate the database maintenance process, refer to the section *Maintenance (F11)* on page 37 of the Administrative Functions chapter in this manual.

Periodic Safety Checks

It is recommended that the following checks be performed on the transmitter every 24 months:

- Inspect the transmitter for mechanical and functional damage
- Inspect the relevant safety labels for legibility

If the labels are not legible, call Nellcor's Technical Services Department at 1.800.635.5267 or contact your local Nellcor representative.

Cleaning



Caution: Do not spray, pour, or spill any liquid on any of the Oxinet III components, its accessories, connectors, switches, or openings in the chassis, since this may damage the Oxinet III system.

To clean the pager or Central Station screens, use a clean cloth designed for use on lenses or touch-sensitive screens. To clean the pager or Central Station casings, use a clean damp cloth and wipe dry.

For surface-cleaning and disinfecting the transmitter, follow your institution's procedures or:

- Surface-clean by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wipe the surfaces of the transmitter.

- Disinfect by using a soft cloth saturated with Glutaraldehyde (CIDEX™ or equivalent) or 10% chlorine bleach in tap water.

Spare Parts

To order spare parts, contact Nellcor's Technical Services Department at 1.800.635.5267. Spare parts and part numbers are shown in tables 6 and 7. A parts list for the Oxinet III system is also available on-line at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/apartweb/main/partaccemenu.html

Table 6: Parts List

Description	Part Number
Access Point	APOXI3
Transmitter	10001952
Communication Server	CS16OXI3
Pager	10005478
Router/Switch	ROUTOXI3

Table 7: Accessories List

Description	Part Number
Antenna, Pager Transmitter	X3440098
Pager Clip-on Holder	10005477
Power Supply, Access Point	APPSOXI3
Transmitter, Pager	PAGETRAN
Power Supply, Pager Transmitter	X3440097
UPS, Uninterruptible Power Supply	UPSOXI3
USB Memory Device	10001957

Returning Components

Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Nellcor warranty.

1. Contact your supplier or local Nellcor office (Technical Services Department, 1.800.635.5267) for a returned goods authorization (RGA) number. They will also provide you with the address for returning the Oxinet III component.
2. Pack the component(s). The best method for returning the component(s) is to pack them in the original shipping carton. If the original shipping carton is not available, use another suitable carton, using sufficient padding to protect the component. Mark the shipping carton and any shipping documents with the RGA number. Return the component(s) by any method that provides proof of delivery.

Troubleshooting

Troubleshooting List

Table 8 lists troubleshooting tips for some of the problems that might occur while operating the Oxinet III system.

Some problems might indicate equipment malfunction. Your Oxinet III Administrator should be contacted to resolve these types of problems. You can also contact Nellcor's Technical Services Department at 1.800.635.5267.

Table 8: Troubleshooting

Symptom	Cause	Corrective Action
Message appears: <i>Please wait..Maintenance is running. This should take few minutes to complete.</i>	The Oxinet III software performs database maintenance automatically: the software temporarily closes the program, performs database file maintenance, and relaunches the program at 10:05 am every day. This maintenance procedure normally takes less than 45 seconds to run. During this brief period, the system does not process any incoming data, including alarms.	No intervention is needed.
Poor cursor control on the Central Station	The cursor may need to be aligned.	<ul style="list-style-type: none"> Connect a keyboard to the Central Station and restart it. Press the F7 key on the keyboard, then type the Administrative function password. When the <i>Elo Touchscreen Properties</i> dialog box opens, press the Align button. The system will guide you through the alignment process. When complete, press the OK button on the <i>Elo Touchscreen Properties</i> dialog box to close this function.
Software Activity Indicator (colored bars in upper left corner of screen) stop scrolling	Software activity has stopped.	<ul style="list-style-type: none"> Restart the Central Station. <p>If problem still exists, contact Nellcor's Technical Services Department at 1.800.635.5267.</p>
No display on the Central Station	The Central Station may have lost power.	<ul style="list-style-type: none"> Ensure that the AC power cord is connected to the power input jack on the back of the base of the Central Station and the other end is plugged into one of the battery backed-up AC outlets or the UPS.
	The UPS has drained its battery.	<ul style="list-style-type: none"> Recharge the battery on the UPS. Replace the battery if necessary.
	The UPS is not operating properly.	<ul style="list-style-type: none"> Replace the UPS.

Table 8: Troubleshooting (Continued)

Symptom	Cause	Corrective Action
No current data is being displayed for an active oximeter or several oximeters	Data from an active oximeter is not reaching the Central Station.	<ul style="list-style-type: none"> Make sure cable is securely connected to oximeter's data port Check that router/switch has power <p>Wired configuration:</p> <ul style="list-style-type: none"> Check connection between oximeter and communication server Check that communication server has power. Check connection between communication server and router/switch. <p>Wireless configuration:</p> <ul style="list-style-type: none"> Check that transmitter has power. Check connection between oximeter and transmitter. Check that access point has power.
No current data is being displayed for any oximeters in the Oxinet III system.	Data from all active oximeters is not reaching the Central Station.	<ul style="list-style-type: none"> Check that the Cat 5 cable connecting the router/switch to the Central Station is securely connected to any of the router/switch's numbered ports. Check that the other end of the Cat 5 cable is securely connected to the network port connection on the back of the Central Station. Check that the router/switch has power. <p>Wired configuration:</p> <ul style="list-style-type: none"> Check that the communication server has power. Check connection between communication server and router/switch. <p>Wireless configuration:</p> <ul style="list-style-type: none"> Check that access point has power. Check connection between access point and router/switch.
A pager does not receive an alarm page	The pager may not be assigned to that patient or the pager may have been out of range.	<ul style="list-style-type: none"> Check the Pager Assignments on the Central Station to confirm that the pager is assigned to the room/patient where the alarm occurred.
Multiple pagers do not receive an alarm	The pager transmitter may have lost power or the cord connecting the pager transmitter with the Central Station may be loose or disconnected.	<ul style="list-style-type: none"> Confirm the red power light for the pager transmitter is on Confirm the power supply is still connected to the pager transmitter. Check the cord connecting the Central Station to the pager transmitter to ensure it is securely connected to the serial port of the pager transmitter and the COM1 port of the Central Station.

Table 8: Troubleshooting (Continued)

Symptom	Cause	Corrective Action
The Central Station is frozen	Program error	<ul style="list-style-type: none"> Restart the Central Station. If problem still exists, contact Nellcor's Technical Services Department at 1.800.635.5267.
	Central Station computer error	<ul style="list-style-type: none"> Restart the Central Station. If problem still exists, contact Nellcor's Technical Services Department at 1.800.635.5267.
Alarms not audible	Alarm is not configured as an audible alert.	<ul style="list-style-type: none"> Press F10 key on the keyboard: <ol style="list-style-type: none"> When the uShield dialog box appears, type 1234 for the password and press Ok button. In the Oxinet Control Panel, set the type of audible alarm you desired. See <i>Oxinet Control Panel (F10)</i> on page 30 for details.
	Volume is turned off/down for speakers.	<ul style="list-style-type: none"> Press F8 key on the keyboard: <ol style="list-style-type: none"> When the uShield dialog box appears, type 1234 for the password and press Ok button. In Volume Control dialog box, raise the volume by clicking and dragging the Volume slider up. See <i>Adjusting Volume (F8)</i> on page 21 for details.

Obtaining Technical Assistance

For technical information and assistance, or to order parts or a service manual, contact Nellcor's Technical Services Department at 1.800.635.5267 or your local Nellcor representative.

The latest versions of this operator's manual and the service manual are available online, along with other Nellcor oximetry manuals, at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Specifications

Physical Design Requirements

Table 9: Central Station

CPU	Minimum 500 MHz processor
Memory	Minimum 256 MB SDRAM
Display	Minimum 12.1" LCD with 800x600, 18-bit color, 250CD/m2 brightness
Touchscreen	EloTouch
Wireless	802.11b/g
I/O	1 or more RS-232 ports 1 x Parallel port 2 x USB 1.1
Physical Dimensions	367 mm W x 323 mm H x 348 mm D (14.4" W x 12.7" H x 13.7" D)
Weight	approximately 18 lbs
Storage Temperature	-20 to 60°C (-4 to 140°F)
Operating Temperature	0 to 45°C (32 to 113°F)
Altitude	0 to 3048 meters (0 to 10,000 feet)
Relative Humidity	10% to 95% non-condensing

Table 10: Transmitter

Physical Dimensions	6.93" W x 1.9" H x 4.26" D
Connections	Power Port RS-232 Port
Visual Indicators	Power and Communication Indicators
Power	Power use approx. 100mW Operating range: 90-264 VAC and 47-63 Hz
Malfunction Indicator	Transmitter has an audible or visual indicator of a pulse oximeter failure to communicate
Storage Temperature	-20 to 60°C (-4 to 140°F)

Table 10: Transmitter

Operating Temperature	0 to 45°C (32 to 113°F)
Altitude	0 to 3048 meters (0 to 10,000 feet)
Relative Humidity	5% to 95% non-condensing

Table 11: Access Point

Physical Dimensions	7.75" W x 1.25" H x 5.5" D
Frequency Range	2.4 to 2.5 GHz
Data Rate	2 Mbps
Output Power	500 mW
Power Management	Receive: 500 mW = 375 mA @ 5V Transmit: 500 mW = 500-675 mA @ 5V
Operating Temperature	0 to 54°C (32 to 130°F)
Storage Temperature	-21 to 60°C (-5 to 140°F)

Table 12: Communication Server

Physical Dimensions	16.93" W x 1.77" H x 9.01" D
Connections	RS-232 Ports; RJ-45 Network Connections
Visual Indicators	Power and Communication Indicators
Power	Autoranging 110V - 240V
Operating Temperature	0 to 40°C (32 to 104°F)
Storage Temperature	-30 to 70°C (-22 to 158°F)
Relative Humidity	5% to 95% non-condensing

Table 13: Router/Switch

Ports	10/100 RJ-45 Switched Ports
Indicators	Power, Ethernet, Internet
Network Protocol	TCP/IP
Physical Dimensions	7.32" W x 1.89" H x 6.06" D
Weight	12.28 oz
Power Input	External 9 VAC, 100mA
Operating Temperature	0 to 40°C (32 to 104°F)

Table 13: Router/Switch

Storage Temperature	-20 to 70°C (-4 to 158°F)
Operating Humidity	10% to 85% non-condensing
Storage Humidity	5% to 90% non-condensing

Table 14: Pager Transmitter

Physical Characteristics	8.5" W x 8.5" H x 2" D wall mountable Weight: 1.5 lb
Power Supply	12VDC 2A AC/DC Adapter
RF Power Out	5 watts nominal, configurable to 2 watts
Frequency	VHF: 148-174 MHz, UHF1: 400-430 MHz, UHF2: 440-470 MHz
Operating Temperature	0 to 28°C (32 to 82°F)

Table 15: Pager

Physical Characteristics	2.76" W x 1.89" H x 0.79" D Weight: 1.76 ounces (including battery) Minimum: 60-message storage memory, up to 500 characters per message
Power and battery life	Standard AAA alkaline batteries Battery life: at least 700 hours under typical use (has a low-battery indicator)
Display	2-Line Alphanumeric display, 36-character
Display Lighting	Button activation
Storage Temperature	-20 to 60 °C (-4 to 140 °F)
Operating Temperature	-10 to 50 °C (14 to 122 °F)
Relative Humidity	Up to 95% 50 °C (non-condensing)

Compliance

Table 16: Compliance Information

Item	Compliant with
Equipment classification	Safety Standards: IEC 60950-1 IEC 60601-1-1 Compliant UL 60950 EN60950
Marking and Instructions	IEC 60950-1, Sub-clause 1.7
Protection from hazards	IEC 60950-1, Sub-clause 2
Wiring connections and supply	IEC 60950-1, Sub-clause 3
Comply with IEC 60950 or relevant component standard	IEC 60950
Protection against ingress of water	IEC 60950-1, Sub-clause T IPX1
Electromagnetic emissions	FCC Part 15:2002 CLASS B
Power interface	IEC 60950-1, Sub-clause 1.6
Thermal requirements	IEC 60950-1, Sub-clause 4.5
Resistance to fire	IEC 60950-1, Sub-clause 4.7

This device has been tested and found to comply with FCC Part 15 "Class B" regulations for digital devices. Operation is subject to the following two conditions:

- This device may not cause harmful interference and
- This device must accept any interference that may cause undesired operation

These FCC limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential or commercial environment. This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with this operator's manual and the service manual, may cause harmful interference to radio communications.

IEC 60601-1-1 Compliance

The following information provides instructions and guidance regarding the use of the Nellcor N-395, N-550, N-595, N-560, and N-600 pulse oximeters. These oximeters have been found to be compliant with IEC 60601-1-1, when used in a system level configuration with the AC Y-Cord and the Oxinet III transmitters.

Note that the AC Y-Cord is designed with one AC plug connection to AC mains power and with two (IEC-320 style) connectors for powering an oximeter and a transmitter.

The requirements listed below must be followed:

1. This system is authorized for use in the USA only.
2. The AC mains voltages must be in the range of 100 to 132 VAC.
3. The combinations of equipment listed below are authorized to be in the patient environment.
 - N-395 with Oxinet III transmitter, both AC powered by AC Y-Cord.
 - N-550 with Oxinet III transmitter, both AC powered by AC Y-Cord.
 - N-595 with Oxinet III transmitter, both AC powered by AC Y-Cord.
 - N-560 with Oxinet III transmitter, both AC powered by AC Y-Cord.
 - N-600 with Oxinet III transmitter, both AC powered by AC Y-Cord.



Note: When using Oxinet III, use only “Lead Year, Model ADP-0502-5V AC/DC Adapter.” The adapter is connected to mains power via the AC Y-Cord.



WARNING: No other devices are intended to be used with the AC Y-Cord. The use of equipment not specified in this document may subject the patient to excessive leakage current. The Oxinet III has a DB-9 connector with a metal shell. Do not touch the metal shell and the patient simultaneously. High leakage current is possible in case of ground failure of the PSU. During cleaning, sterilization, disinfection or adjustment of any kind, the instructions contained in this manual must be followed.

Please contact the Nellcor’s Technical Service Department at 1.800.635.5267 if you have any questions regarding the proper use of the system.

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